



DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR part 71

[CDC Docket No. CDC-2023-0051]

RIN 0920-AA82

Control of Communicable Diseases; Foreign Quarantine: Importation of Dogs and Cats

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services (HHS), proposes to amend its foreign quarantine regulation to provide additional clarity and safeguards to address the public health risk of dog-maintained rabies virus variant (DMRVV) associated with the importation of dogs into the United States. The United States has been DMRVV-free since 2007, and reintroduction poses significant risk to human and animal health. The close relationship between dogs and people means there is a direct public health risk to individuals that interact with inadequately vaccinated dogs imported from countries at high risk of DMRVV (high-risk countries). The notice of proposed rulemaking (NPRM) also addresses the importation of cats because both dogs and cats are included in the current regulation. Cats are not required to have proof of rabies vaccination and CDC is not proposing new substantive changes relating to the importation of cats.

DATES: Written or electronic comments on the NPRM must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Written comments on the proposed data collection requirements under the Paperwork Reduction Act must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: For the NPRM: You may submit comments, identified by Docket No. CDC-2023-0051 or RIN 0920-AA82, by either of the following ways:

- Federal Rulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H16-4, Atlanta, GA 30329.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this action. All relevant comments received, including any personal information provided, will be posted without change to <https://www.regulations.gov/>. Do not submit comments by email. CDC does not accept comments by email.

To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7570; E-mail: omb@cdc.gov.

FOR FURTHER INFORMATION CONTACT: Ashley C. Altenburger, J.D., Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H16-4, Atlanta, GA 30329. Telephone: 1-800-232-4636. For information regarding CDC operations and importations related to this NPRM, please contact Dr. Emily Pieracci, D.V.M., Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H16-4, Atlanta, GA 30329; Telephone: 1-800-232-4636.

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I. Executive Summary

A. Purpose of this Regulatory Action

Through this NPRM, HHS/CDC proposes to revise its regulation at 42 CFR 71.51 to prevent the reintroduction and spread of dog-maintained rabies virus variant (DMRVV) in the United States. HHS/CDC also proposes amendments to 42 CFR 71.50, which contains definitions applicable to animal importations under 42 CFR part 71, subpart F. The United States was declared DMRVV-free in 2007.¹ The importation of just one dog infected with DMRVV risks re-introduction of the virus into the United States; such a public health threat could result in the loss of human and animal life and consequential economic impact.^{2, 3, 4} The rabies virus can infect any mammal, and, once clinical signs appear, the disease is almost always fatal.⁵ A

¹ Centers for Disease Control and Prevention. US Declared Canine-Rabies Free. <https://www.cdc.gov/media/pressrel/2007/r070907.htm>. Accessed June 1, 2023.

² World Bank (2012). People, Pathogens and Our Planet: The Economics of One Health. Retrieved from <https://openknowledge.worldbank.org/handle/10986/11892>.

³ Raybern, C et al. Rabies in a dog imported from Egypt-Kansas, 2019. *MMWR Morb Mort Wkly Rep* 2020; 69 (38): 1374-1377.

⁴ Jeon S, Cleaton J, Meltzer M, et al. Determining the post-elimination level of vaccination needed to prevent re-establishment of dog rabies. *PLoS Neg Trop Dis* 2019; 13 (12): e0007869.

⁵ Fooks AR, Banyard AC, Horton DL, Johnson N, McElhinney LM, Jackson AC. Current status of rabies and prospects for elimination. *Lancet* 2014;384:1389–99.

DMRVV-infected dog can transmit the virus to humans, domestic pets, livestock, or wildlife. Importing inadequately vaccinated dogs from countries at high risk of DMRVV (high-risk countries)⁶ involves a significant public health risk to people who directly interact with those dogs. In 2019, the importation of a DMRVV-infected dog cost the affected State governments more than \$400,000 U.S. dollars (USD) for the ensuing public health investigations and rabies post-exposure prophylaxis (PEP) treatments administered to exposed persons.^{7, 8}

Through this proposed rulemaking, HHS/CDC also seeks to prevent and deter the importation of dogs with falsified or fraudulent rabies vaccine documentation. In 2020, CDC observed a 52 percent increase in the number of dogs that were ineligible for admission due to falsified or fraudulent documentation, as compared to 2018 and 2019 (450 dogs compared to the previous baseline of 300 dogs per year).⁹ This troubling trend continued in 2021, with an additional 24 percent increase of dogs ineligible for admission in just the first half of the year, compared to the full 2020 calendar year (January-December) (approximately 560 dogs with falsified or fraudulent documentation).¹⁰

The use of a single false rabies vaccination certificate (RVC)¹¹ or rabies vaccination documents as part of a larger shipment of multiple dogs raises suspicion that the other rabies vaccination documents for the remaining dogs may also be false and creates an additional burden on CDC and State health departments to track, test, and evaluate the remaining dogs in the shipment. CDC and U.S. Customs and Border Protection (CBP) have documented numerous

⁶ A complete list of countries with high risk of DMRVV is available at “High-Risk Countries for Dog Rabies.” <https://www.cdc.gov/importation/bringing-an-animal-into-the-united-states/high-risk.html>. Accessed June 8, 2023.

⁷ Raybern, C et al. Rabies in a dog imported from Egypt-Kansas, 2019. *MMWR Morb Mort Wkly Rep* 2020; 69 (38): 1374-1377.

⁸ Centers for Disease Control and Prevention (2022). Rabies Postexposure Prophylaxis. Retrieved from https://www.cdc.gov/rabies/medical_care/index.html.

⁹ Centers for Disease Control and Prevention. Quarantine Activity Reporting System (version 4.9.8.8.2.2A). Dog importation data, 2018-2020. Accessed: 15 February 2021.

¹⁰ Centers for Disease Control and Prevention. Quarantine Activity Reporting System (version 4.9.8.8.2.2A). Dog importation data, January 1, 2021- July 14, 2021. Accessed: 01 October 2021.

¹¹ Centers for Disease Control and Prevention. What is a valid rabies vaccination certificate? Available at: www.cdc.gov/importation/bringing-an-animal-into-the-united-states/vaccine-certificate.html

importations every year in which flight parents¹² transport dogs for the purpose of resale, adoption, or transfer of ownership that do not meet CDC's entry requirements. These flight parents often claim the dogs are their personal pets to avoid U.S. Department of Agriculture (USDA) Animal Care entry requirements and potential tariffs or fees under CBP regulations. Even when well-meaning, these importers jeopardize public health, as many of them do not know the history of the animals they are transporting. Deterring individuals who serve as flight parents from supporting fraudulent dog importations has proven difficult despite the existence of CBP penalties relating to aiding unlawful importations and fraudulent conduct. *See* 19 U.S.C. 1592 and 19 U.S.C. 1595a.

The documented increase in fraudulent vaccine documentation and importers circumventing dog import regulations was shortly followed by the advent of the coronavirus disease 2019 (COVID-19) pandemic. Many public health resources were redirected to the COVID-19 response, reducing the availability of resources to respond to dog importation issues. In light of this confluence of events, in June 2021, CDC published a temporary suspension of dogs entering the United States from DMRVV high-risk countries.¹³ The temporary suspension created a system that, among other things, implemented the use of standardized forms, required titer test results demonstrating the presence of rabies antibodies in dogs, and developed a reservation system allowing for the rapid quarantine of dogs from DMRVV high-risk countries arriving with inadequate proof of titers. During the temporary suspension, CDC has documented decreased instances of fraud, fewer dogs being denied admission into the country, fewer sick and dead dogs arriving in the United States, and fewer federal and state agency resources devoted to

¹² A flight parent refers to a person accompanying an animal into the country. Flight parents are often solicited through social media, not affiliated with the sponsoring dog rescue organization, and usually compensated with an airline ticket or other funds.

¹³ Temporary Suspension of Dogs Entering the United States from High-Risk Rabies Countries. *Federal Register*, 86 Fed. Reg. 32041 (June 16, 2021).

addressing issues related to inadequately vaccinated dogs upon arrival. This NPRM proposes a similar regulatory framework based on the documented successes of the temporary suspension.

In parallel with the publication of this NPRM, CDC has published an extension of the temporary suspension through July 31, 2024. A suspension remains necessary to protect the public's health against the reintroduction of DMRVV into the United States because there is a continued threat posed by dogs from DMRVV high-risk countries that are unvaccinated or inadequately vaccinated against rabies. This continued threat is due to various factors, including: a high volume of dogs being imported into the United States contemporaneous with insufficient veterinary controls in DMRVV high-risk countries to prevent the export of inadequately vaccinated dogs, inadequate veterinary supply chains for vaccines and related materials, and persistent workforce capacity shortages, particularly in DMRVV high-risk countries that export dogs to the United States.

This NPRM proposes to incorporate practices used during the temporary suspension period that CDC found effective to better protect the public's health from introductions of DMRVV from high-risk countries and reduce potential instances of fraudulent documentation. The NPRM outlines a framework and set of operations that CDC believes would mitigate the need for suspending dog imports from high-risk countries should these procedures be adopted. We welcome feedback from the public on all proposals contained within this NRPM.

B. Summary of Major Provisions

In this NPRM, HHS/CDC proposes to align U.S. import requirements for dogs with the importation requirements of other DMRVV-free countries by requiring proof of rabies vaccination and adequate serologic test results from a CDC-approved laboratory. This NPRM proposes for all dog imports: a microchip, six-month minimum age requirement for admission, importer submission of a CDC import form (*CDC Import Submission Form*), and requirements

for airlines to confirm documentation, provide safe housing, and assist public health officials in determining animal cause of death.

HHS/CDC proposes all importers of dogs that have been in a DMRVV high-risk country in the past six months, regardless of whether foreign- or U.S.-vaccinated, would be required to submit a standardized vaccination form verifying the rabies vaccination status of dogs. For dogs that have been in a DMRVV high-risk country in the past six months and have a valid U.S.-issued rabies vaccination certificate, this NPRM proposes that the dog be required to arrive at a U.S. airport with a CDC quarantine station. For dogs that have been in a DMRVV high-risk country in the past six months, and were vaccinated in a foreign country, this NPRM proposes that the dog be required to arrive a U.S. airport with a CDC quarantine station and a CDC-registered Animal Care Facility. This NPRM further proposes that dogs imported from DMRVV-free or DMRVV low-risk countries be eligible to arrive at any U.S. port. In lieu of a CDC vaccination form, which would be required for dogs imported from DMRVV high-risk countries, these importers may instead provide proof that the dogs have only been in DMRVV-free or DMRVV low-risk countries during the previous six months prior to arriving in the United States.

HHS/CDC also proposes to require that all dogs arriving from any country, including dogs returning to the United States after traveling abroad, be properly microchipped with an International Standards Organization (ISO)-compatible microchip prior to travel into the United States. The microchip information would be included on importation documents to help ensure that dogs presented for admission are the same dogs as those listed on the rabies vaccination records. Microchips are already used globally and required for importation in many DMRVV-free countries. Microchips are recommended by the international veterinary community and

animal rescue and welfare organizations to reunite lost animals with their owners and ensure the veterinary records for an animal can be linked to the animal.¹⁴

The microchip requirement will also promote greater confidence in the information recorded on the rabies vaccination records. CDC has documented several instances of importers attempting to present records of vaccinated dogs that became ill or died before travel as the vaccination records for dogs that lacked appropriate veterinary paperwork, presenting the original dogs' vaccination records for the replacement dogs and attempting to import the unvaccinated dogs into the United States without detection.¹⁵ Because microchips are not currently required for entry into the United States and the dogs in question were not microchipped, the public health investigation to confirm the identity of these dogs was both resource intensive and challenging. Further, during CDC's temporary suspension of dogs entering the United States from DMRVV high-risk countries, CDC documented that 99 percent (>20,000) of permit applications received were for dogs that had microchips implanted prior to the announcement of the suspension. Microchips are frequently used by pet owners and required for international transit by many foreign countries. Therefore, CDC's proposed requirement would have minimal impact on dog importations, although costs to some importers would still be incurred. We welcome feedback on this proposal.

To address concerns about importations of puppies that are too young to be properly vaccinated against rabies, through this NPRM, HHS/CDC proposes requiring that any dog arriving in the United States be at least six months of age. Dogs cannot be vaccinated effectively against rabies before 12 weeks of age and are not considered fully vaccinated until 28 days after vaccination.¹⁶ Establishing a six-month minimum age requirement for the import of dogs aligns

¹⁴ American Veterinary Medical Association. Microchipping FAQ. <https://www.avma.org/resources-tools/pet-owners/petcare/microchips-reunite-pets-families/microchipping-faq>. Accessed June 1, 2023.

¹⁵ Centers for Disease Control and Prevention. Quarantine Activity Reporting System (version 4.9.8.8.2.2A). Dog importation data, 2018-2020. Accessed: February 15, 2021.

¹⁶ National Association of State Public Health Veterinarians. Compendium of animal rabies prevention and control, 2016. *JAVMA* 2016; 248 (5):505-517.

with current USDA requirements for commercial dog imports under the Animal Welfare Act¹⁷ and will better protect the public's health from rabies. Under this proposal, an exception would be included to permit an owner to import a maximum of three individual (personal pet) dogs under six months of age in the same calendar year (January–December) if arriving in the United States via a U.S. land port through Canada or Mexico, provided the dogs have not been in a DMRVV high-risk or DMRVV-restricted country since birth. CDC notes that both Canada and Mexico are currently DMRVV-free countries, and a limited exception to accommodate personal pet owners who travel by land between the U.S. and Canada or Mexico is unlikely to threaten the public's health. HHS/CDC specifically welcomes public comment this proposal.

In this NPRM, HHS/CDC also proposes to require all dog importers to submit a *CDC Import Submission Form* (i.e., an online form that includes the importers' contact information and information related to each dog being imported) via a CDC-approved system prior to travel to the United States. This proposed requirement would apply to all imported dogs (including dogs arriving from DMRVV-free and DMRVV low-risk countries) arriving in the United States by air, land, or sea. Upon arrival at a U.S. port,¹⁸ importers will present a receipt confirming they submitted a completed *CDC Import Submission Form*; additionally, importers arriving by air will present the receipt to the airline prior to boarding. The receipt will contain the information submitted on the *CDC Import Submission Form*, which will allow government officials to verify that the details from the *CDC Import Submission Form* match the dog being presented for entry. CDC's import submission system would operate as a free online system. Requiring documentation for all imported dogs would allow CDC to track the total number of dog importations (including the number imported from DMRVV high-risk countries), something CDC is unable to do currently.

¹⁷ 7 U.S.C. 2148.

¹⁸ U.S. Port means any seaport, airport, or border crossing point under the control of the United States. 42 CFR 71.1(b).

HHS/CDC further proposes that an airline, prior to accepting a dog for transport, must confirm that the dog possess all required import documentation based on the country of origin. Airlines must also ensure dogs from DMRVV high-risk countries will only be entering the United States through a designated U.S. airport with a CDC quarantine station (if U.S.-vaccinated) or a U.S. airport with both a CDC quarantine station and a CDC-registered Animal Care Facility (if foreign-vaccinated) and that the importer possesses a reservation with the CDC-registered Animal Care Facility for examination, vaccination, and quarantine (if required). As needed, CDC will coordinate with the airline regarding transport of the dog to the CDC-registered Animal Care Facility. These regulatory actions (if finalized as proposed) would help ensure that dogs arriving in the United States from DMRVV high-risk countries are adequately protected against rabies and do not pose a public health threat. We welcome feedback from the public on this proposal.

HHS/CDC proposes to require that airlines return dogs or cats denied admission to the country of departure within 72 hours after arrival. The responsibility for a dog or cat pending admission into the United States or awaiting return to the country of departure has been a point of confusion for many airlines, resulting in delayed care and improper housing for numerous animals. Delays in returning dogs to their countries of departure also potentially threaten U.S. public health by exposing people to dogs with unknown rabies vaccination status. HHS/CDC proposes that the airline on which a dog or cat is brought to the United States must arrange for and ensure transportation and care until the animal is either returned to the country of departure or cleared for entry into the United States.

HHS/CDC also proposes a provision regarding dogs and cats that die *en route* to the United States or that die while detained pending determination of their admissibility. This provision is primarily directed at airlines and would require that they transport deceased dogs and cats and arrange for necropsy requiring gross and histopathologic examination and any subsequent infectious disease testing based on the findings. The importer is responsible for all

costs associated with necropsy and testing. The airline would also be required to notify the CDC quarantine station of jurisdiction¹⁹ prior to transporting a dead dog or cat for a necropsy to determine whether rabies testing is required and provide the quarantine station with the final necropsy report and all test results. These measures will help CDC rule out foreign animal diseases of public health concern²⁰ as a potential cause of death and will protect both animal and human health. The provisions of this paragraph may also be applied to other carriers transporting such dogs and cats in the very rare event when the death of a dog or cat occurs *en route* to the United States, or the animal dies while detained pending determination of their admissibility. HHS/CDC welcomes public comment specifically on these proposed requirements.

Through this NPRM, HHS/CDC proposes to remove the current requirement for a valid RVC in 42 CFR 71.51(c) and replace it with new rabies vaccination forms for dogs imported from DMRVV high-risk countries. The proposed rabies vaccination forms would include the rabies vaccination status of the dog and other required information similar to the current valid RVC requirement. However, unlike the current requirement for a valid RVC, the proposed rabies vaccination forms would be standardized.

The rabies vaccination form for foreign-vaccinated dogs would also be certified by a government official in the exporting country, as an added measure to prevent falsification. The acceptable rabies vaccination form to fulfill this requirement for foreign-vaccinated dogs from DMRVV high-risk countries would be titled “*CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States.*” This proposed change would help ensure that foreign-vaccinated dogs imported from DMRVV high-risk countries meet CDC entry requirements prior to traveling to the United States and allow for

¹⁹ CDC quarantine station jurisdictions, available at: www.cdc.gov/quarantine/quarantinestationsjurisdictionscountries.html.

²⁰ U.S. Department of Agriculture. Notifiable Diseases and Conditions. <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/nvap/NVAP-Reference-Guide/Animal-Health-Emergency-Management/Notifiable-Diseases-and-Conditions>.

follow-up with the exporting country's government officials if repeated import violations occur. HHS/CDC welcomes public comment on this proposed requirement.

Under the proposed rule, importers of U.S.-vaccinated dogs presenting for re-entry into the United States from countries at high risk for DMRVV would be required to arrive at a U.S. airport with a CDC quarantine station. Additionally, prior to traveling out of the United States, a USDA-Accredited Veterinarian would need to complete and sign a form titled "*Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States.*" This form would then be certified by a USDA Official Veterinarian prior to departing the United States and would need to be presented by the importer to the airline to board the dog on its return flight to the United States. The importer would also need to present this form when requested to do so by U.S. government officials upon arrival. The use of this form would decrease the likelihood of falsification or fraud because it would include information in a standardized format and rely on USDA's existing veterinary accreditation system. Dogs arriving with this form would not be subject to the requirement for veterinary examination (unless ill, injured, or exposed), revaccination, verification of adequate rabies serologic tests, and/or post-vaccination quarantine at a CDC-registered Animal Care Facility.

In this NPRM, CDC/HHS proposes to require importers of foreign-vaccinated dogs from DMRVV high-risk countries to enter the United States through an airport with a CDC quarantine station and a CDC-registered Animal Care Facility. The importer would also need to obtain a rabies serologic test from a CDC-approved laboratory for their foreign-vaccinated dogs demonstrating adequate titer levels. In addition, the importer would also need to have a reservation at the CDC-registered Animal Care Facility and have their dog(s) undergo a veterinary exam and revaccination with a USDA-licensed rabies vaccine at the CDC-registered Animal Care Facility. Importers of foreign-vaccinated dogs who cannot obtain serologic test results prior to importation would be required to have their dog remain under quarantine at the facility for 28 days after revaccination or until verification of adequate rabies serologic test from

a CDC-approved laboratory is obtained, whichever occurs first. HHS/CDC is requesting comment on this proposed process.

HHS/CDC proposes a narrow exception for both U.S.- and foreign-vaccinated service dogs that have been in a DMRVV high-risk country within the last six months. This exception would allow such dogs to enter the U.S. at a U.S. seaport if the dog is at least six months of age, has a microchip, has either a complete, accurate, and valid *Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States* form or a complete, accurate, and valid *CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States* form, as appropriate, and has sufficient and valid titer results from a CDC-approved laboratory (if the dog is foreign-vaccinated). To be considered a valid service dog, the dog would need to meet the definition of a “service animal” under 14 CFR 382.3, be accompanied by an “individual with a disability” as defined under 14 CFR 382.3, and work or perform tasks directly related to that individual's disability. HHS/CDC is requesting comment on this proposed exception. HHS/CDC also proposes to prohibit or otherwise restrict importation of dogs into the United States from certain countries that have a history of exporting dogs infected with DMRVV to other countries or have demonstrated a lack of appropriate veterinary controls to prevent the exportation of rabid dogs. To implement this provision, HHS/CDC proposes to maintain a “List of DMRVV-Restricted Countries” from which the importation of dogs into the United States would be prohibited. The list of DMRVV-restricted countries would be maintained on CDC’s website. Additions or removals of countries would also be announced in notices published in the *Federal Register*. Under this proposal, CDC would retain the ability to issue a special exemption on an extremely limited basis for dogs that have been in a DMRVV-restricted country in the six months prior to their importation into the United States (e.g., for dogs imported for scientific purposes, for use as a trained service animal for

individuals with disabilities,²¹ or in furtherance of an important government interest). HHS/CDC welcomes public comment on public health standards and evidence used to maintain a list of DMRVV-restricted countries and the length of time or conditions to be met before a country is added or eligible for removal from the list. Additionally, HHS/CDC welcomes public comment on how the list will be maintained and whether publication on CDC's website and through *Federal Register* notices would be sufficient to adequately inform importers.

HHS/CDC proposes that airlines be required to confirm prior to boarding that the dog is scheduled to arrive at an approved U.S. airport and, if foreign-vaccinated, that the importer has documentation confirming a reservation at the CDC-registered Animal Care Facility. This will ensure that CDC and USDA can follow up with airlines more easily to ensure animals are being properly handled (e.g., not left in cargo warehouses for prolonged periods of time that endanger the health of the animal). Additionally, to address concerns relating to the movement of dogs or cats that are sick or dead upon arrival, HHS/CDC proposes to require that airlines transport all sick or dead animals (regardless of vaccination status and country of origin) to a CDC-registered Animal Care Facility or, under certain conditions, to other CDC- or USDA-approved veterinary clinic within six hours of arrival. CDC acknowledges that extraordinary circumstances, such as extreme weather, may delay the transport of animals beyond the six-hour window. Under such circumstances, CDC will work closely with airlines to address these rare and unforeseen events while ensuring the safe handling of animals. CDC also will work with importers who arrive at unapproved U.S. ports based on circumstances beyond their control (e.g., re-routing of their flight due to extreme weather). CDC quarantine station staff are available 24 hours a day to assist streamlined coordination and processing of dog and cat importation at U.S. ports and provide

²¹ Emotional support animals are not recognized as service animals. U.S. Department of Transportation. Service Animals. <https://www.transportation.gov/individuals/aviation-consumer-protection/service-animals>, last updated June 9, 2021.

coverage for geographic areas beyond the U.S. port in which the CDC quarantine station is located.

HHS/CDC also proposes establishing requirements for businesses that wish to become CDC-registered Animal Care Facilities. Requirements would include a USDA intermediate handlers license and approval by CBP to act as a CBP-bonded facility with an active Facilities Information and Resource Management System (FIRMS) code. This will ensure dogs and cats receive appropriate veterinary care and are housed in a way that prevents the spread of infectious diseases while protecting the safety of the animals.

The requirements HHS/CDC is proposing in this NPRM for dog importation into the United States are summarized below in Table 1. Since HHS/CDC is not proposing substantial changes to cat importation requirements, Table 1 does not apply to cats.

Table 1. Summary table of proposed importation requirements for dogs based on vaccination status and country of origin				
	Requirements for Admission			
	Age	ISO-Compatible Microchip	Documentation	Approved U.S. Ports
U.S.-Vaccinated Dog from DMRVV High-Risk Country	At least six months of age	Yes	Valid <i>Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States</i> Form and <i>CDC Import Submission</i> Form receipt	Only U.S. airports with a CDC quarantine station*
Foreign-Vaccinated Dog from DMRVV High-Risk Country	At least six months of age	Yes	Reservation with a CDC-registered Animal Care Facility, <i>CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United</i>	Only U.S. airports with a CDC quarantine station and a CDC-registered Animal Care Facility*

			<i>States Form, CDC Import Submission Form</i> receipt, titer results from a CDC-approved laboratory (dogs without titer results will be required to quarantine)	
Dog from Rabies-Free or DMRVV Low-Risk Country	At least six months of age**	Yes	There are no vaccination requirements, however, written documentation that the dog has resided or otherwise been only in a DMRVV low-risk or rabies-free country for the six months prior to the attempted entry and <i>CDC Import Submission Form</i> receipt	All U.S. ports
U.S.- or Foreign-Vaccinated Dog from DMRVV-Restricted Country	At least six months of age	Yes	<i>CDC Dog Import Permit</i> for limited groups of dogs (i.e., service animals, government-owned animals)	Only U.S. airports with a CDC quarantine station and a CDC-registered Animal Care Facility

* Dogs arriving at U.S. land ports that have been in DMRVV high-risk countries within the last six months will be denied admission. All service dogs entering at U.S. seaports must be six months of age, have an ISO-compatible microchip, and have a receipt confirming submission of a *CDC Import Submission Form*. Service dogs that have been in DMRVV high-risk countries within the last six months may enter the United States at U.S. seaports if they have either a valid *Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States* Form or both a valid *CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States* Form and sufficient and valid titer results from a CDC-approved laboratory.

**** Dogs arriving at U.S. land ports are subject to the six-month minimum age requirement.**

However, an importer may import up to three dogs younger than six months of age in a calendar year if the dogs have not been in a DMRVV high-risk country since birth.

The forms HHS/CDC is proposing be required in this NPRM for dog importation into the United States are summarized below in Table 2. Since HHS/CDC is not proposing substantial changes to cat importation requirements, Table 2 does not apply to cats.

Table 2. Summary table of proposed forms required from importers of dogs based on vaccination status and country of origin				
Form	Dog from Rabies-Free or DMRVV Low-Risk Country	U.S.-Vaccinated Dog from DMRVV High-Risk Country	Foreign-Vaccinated Dog from DMRVV High-Risk Country	U.S.-Vaccinated Dog from DMRVV-Restricted Country
<i>CDC Import Submission Form</i>	Required	Required	Required	Required
<i>Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States Form</i>	Not Required	Required	N/A	Required
<i>CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States Form</i>	Not Required	N/A	Required	N/A
<i>Application for Special Exemption for a Permitted</i>	Not Required	Not Required	Not Required	Required

<i>Dog Import Form</i>				
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* Importers of foreign-vaccinated dogs from DMRVV high-risk countries will also be required to provide additional information to the CDC-registered Animal Care Facilities to make a reservation for their dog prior to arrival in the United States.

The documentation HHS/CDC is proposing in this NPRM be presented at the U.S. port upon arrival for dog importation into the United States is summarized below in Table 3. Since HHS/CDC is not proposing substantial changes to cat importation requirements, Table 3 does not apply to cats.

Table 3. Summary table of proposed required documentation to be presented at U.S. port upon arrival for dogs based on vaccination status and country of origin				
Documentation to be Presented at U.S. Port Upon Arrival	Dog from Rabies-Free or DMRVV Low-Risk Country	U.S.- Vaccinated Dog from DMRVV High-Risk Country	Foreign- Vaccinated Dog from DMRVV High-Risk Country	U.S.- Vaccinated Dog from DMRVV-Restricted Country
<i>CDC Import Submission Form Receipt</i>	Required	Required	Required	Required
Written documentation that the animal has resided or otherwise been only in a rabies-free or DMRVV low-risk country for the six months prior to the attempted entry	Required	N/A	N/A	N/A

<i>Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States Form</i>	Not Required	Required	N/A	Not Required
Reservation with a CDC-registered Animal Care Facility	Not Required	Not Required	Required	May be required
<i>CDC Dog Import Permit</i>	N/A	N/A	N/A	Required

C. Costs and Benefits

CDC conducted an analysis to estimate the distributions of costs and benefits that may be incurred if a final rule is published in the future with the requirements proposed in this NPRM. The provisions of this NPRM (if finalized as proposed) are not likely to have an effect on the economy of \$200 million or more in any one year, although there is considerable uncertainty around the number of dogs imported at baseline, including the number of dogs imported from DMRVV high-risk countries. HHS/CDC is soliciting public comment on costs to importers, airlines and other carriers, and State and local health departments of the proposed requirements in this NPRM to improve the accuracy of cost and benefit estimates for a future final rule.

The provisions of this NPRM (if finalized as proposed) will address the market inefficiency in which dog importers do not account for the potential detrimental impacts to public health that may result from the importation of ill dogs, especially dogs infected with DMRVV. Federal regulation is necessary to mitigate the risk of importing infected dogs. Federal action allows risks to be addressed prior to dogs' arrival in the United States and for dogs to be evaluated, revaccinated, and possibly quarantined (if required) in controlled conditions after their arrival in the United States. The regulatory changes proposed in this NPRM (if finalized as

proposed) are expected to affect the following categories of interested parties and implementing partners:

- Importers of dogs from countries that are DMRVV-free or are low risk for DMRVV;
- Importers of dogs from countries that are at high risk of DMRVV;
- Airlines and other carriers;
- CBP;
- CDC;
- USDA; and
- State and local public health and animal health departments.

The changes proposed in the NPRM incorporate different requirements for dogs imported from DMRVV high-risk countries than those imported from DMRVV-free or DMRVV low-risk countries. The annualized and present value estimates of monetized costs and benefits over the 10-year period from 2023 through 2032 using three percent and seven percent discount rates are summarized below. The annualized, monetized costs (2020 USD) of the provisions in the NPRM (if finalized as proposed) are estimated to be \$29 million (range: \$7.7 to \$87 million) using a three percent discount rate; the estimated monetized costs using a seven percent discount rate are largely the same.

Most monetized costs are expected to be incurred by importers (84 percent of costs is the most likely estimate). The estimated monetized costs are about 3.8 times greater for importers of dogs from DMRVV high-risk countries compared to importers of dogs from DMRVV-free or low-risk countries. The provisions proposed in the NPRM estimated to result in the greatest increase in costs for importers of dogs are those associated with the veterinary examination and revaccination against rabies at a CDC-registered Animal Care Facility for foreign-vaccinated dogs from DMRVV high-risk countries in proposed section 71.51(k), costs for titer testing of foreign-vaccinated dogs from DMRVV high-risk countries, additional costs associated with the

proposed *CDC Import Submission Form* requirements and including the information from the form for all dogs in CDC data systems prior to or upon entry, the proposed minimum age for imported dogs, and the proposed microchip requirements for all imported dogs. Other costs include (1) an expected reduction in the number of dogs imported from DMRVV high-risk countries, (2) the proposed requirements to arrive at one of 18 U.S. airports with a CDC quarantine station such that some travelers would need to arrange their travel plans to arrive at these approved U.S. airports (required for U.S.-vaccinated dogs arriving from DMRVV high-risk countries) or a more limited number of U.S. airports with CDC-registered Animal Care Facilities (required for foreign-vaccinated dogs arriving from DMRVV high-risk countries) rather than other airports without CDC staff, and (3) the proposed requirement of obtaining a *CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States* Form or a *Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States* Form with certification by an Official Government Veterinarian for all dogs from DMRVV high-risk countries.

Airlines are estimated to absorb about 8.7 percent of the estimated annualized costs associated with the NPRM (if finalized as proposed). Most airline costs would result from ensuring that all transported dogs comply with the new requirements in the NPRM (if finalized as proposed) and from a small reduction in the number of dogs transported.

CDC is estimated to incur about 6.9 percent of the annualized, monetized costs (most likely estimate) associated with the provisions of this NPRM (if finalized as proposed). Most CDC costs would be associated with the oversight of animal care facilities, which must be approved by and registered with CDC, and the establishment of a laboratory proficiency testing program to support serologic testing for foreign-vaccinated dogs imported from DMRVV high-risk countries. CBP is expected to incur about 0.5 percent of the annualized costs (most likely estimate) associated with the provisions of this NPRM (if finalized as proposed). Most CBP costs would result from training on the proposed new requirements.

The annualized monetized benefits of the provisions in the NPRM (if finalized as proposed) are estimated to be about \$1.9 million (range: \$0.80 to \$4.2 million) using a three percent or seven percent discount rate. Most benefits would accrue to importers (46 percent of the most likely estimates) and to CBP (41 percent of the most likely estimate). Some of the benefits estimated for both importers and CBP would result from reduced time spent on screening dogs from high-risk countries at U.S. ports. The requirements in the NPRM (if finalized as proposed) are estimated to reduce the amount of time required to verify admissibility per dog at U.S. ports because it is assumed that rabies vaccination documentation will be included in standardized forms for importers of dogs from DMRVV high-risk countries. The provisions in this NPRM (if finalized as proposed) are also estimated to reduce the number of dogs arriving ill or dead and the number of dogs denied entry, with benefits estimated for importers, airlines, and CDC.

The wide range between the lower-bound and upper-bound cost and benefit estimates demonstrates that there is considerable uncertainty in these results. At present, the number of dogs imported into the United States is neither accurately nor completely tracked by any data system, and the uncertainty in the cost and benefit estimates reflect uncertainty in both the total number of dogs imported and the number of dogs imported from DMRVV high-risk countries, as well as the cost of the new requirements in the NPRM (if finalized as proposed). The net annualized, monetized costs (total cost estimate – total benefit estimate) were estimated to be about \$26 million per year (range: \$6.9 to \$83 million) using a three percent discount rate. The annualized estimates were relatively unaffected by using a seven percent discount rate.

The importation of just one dog infected with DMRVV risks reintroduction of the virus into the United States, which could result in loss of human and animal life and substantial public

health response costs.^{22, 23, 24} The average cost per importation of a single DMRVV-infected dog is estimated to be \$320,000 (range: \$220,000 to \$520,000) for conducting public health investigations and administering rabies PEP to exposed persons. The primary public health benefit of the provisions in the NPRM (if finalized as proposed) is the reduced risk that a dog with DMRVV will be imported from a DMRVV high-risk country. The above estimate of the cost of importation of a dog with DMRVV does not account for the worst-case outcomes, which include (1) transmission of rabies to a person who dies from the disease, and (2) ongoing transmission to other domestic and wildlife species in the United States. The cost of re-introduction could be especially high if DMRVV spreads to other species of U.S. wildlife. Re-establishment of DMRVV in the United States could result in costly efforts over several years to eliminate the virus again. The costs to contain any reintroduction would depend on the time period before the reintroduction was realized, the wildlife species in which DMRVV was transmitted, and the geographic area over which reintroduction occurs.

An increase in human deaths from DMRVV could occur following the re-introduction of DMRVV to the United States, as the risk of exposure would increase. Human deaths from rabies continue to occur in the United States after exposures to wild animals, and there have been eight deaths among U.S. residents bitten by rabid dogs while traveling abroad in DMRVV high-risk countries since 2009.²⁵ CDC uses the value of statistical life (VSL) to support quantifying benefits for interventions that can result in mortality risk reductions. HHS recommends using a median estimate of \$11.6 million and a range of \$5.5 to \$17.7 million (2020 USD).²⁶ CDC is unable to estimate the potential magnitude of the mortality risk reduction associated with the

²² Smith J, le Gall F, Stephenson S, et al. People, pathogens and our planet. The Economics of One Health 2012;2.

²³ Raybern, C et al. Rabies in a dog imported from Egypt-Kansas, 2019. *MMWR Morb Mort Wkly Rep* 2020; 69 (38): 1374-1377.

²⁴ Jeon S, Cleaton J, Meltzer M, et al. Determining the post-elimination level of vaccination needed to prevent re-establishment of dog rabies. *PLoS Neg Trop Dis* 2019; 13 (12): e0007869.

²⁵ Human Rabies. https://www.cdc.gov/rabies/location/usa/surveillance/human_rabies.html.

²⁶ U.S. Department of Health and Human Services, 2016. Office of the Assistant Secretary for Planning and Evaluation. Guidelines for Regulatory Impact Analysis. https://aspe.hhs.gov/sites/default/files/private/pdf/242926/HHS_RIAGuidance.pdf. Accessed: April 20, 2020.

proposed rule. Based on the median VSL, averting three human deaths per year would mean the benefits of the NPRM (if finalized as proposed) would exceed its costs.

CDC and other Federal government agencies do not know with precision the number of dogs imported each year or the countries from which the dogs originate. More comprehensive data on where dogs are imported from may benefit public health investigations. Arrival data on animals exposed to a dog with DMRVV on U.S.-bound flights, for example, would expedite follow-up of exposed dogs in the United States. The lack of data received from implementing the current regulations also inhibits the Federal government's ability to target interventions for dogs imported from specific countries. Of note, the COVID-19 pandemic weakened rabies control programs in some DMRVV high-risk countries, increasing the risk that imported dogs may be infected with DMRVV.²⁷ The provisions of this NPRM (if finalized as proposed) would be of particular public health benefit in light of the ongoing resource concerns for global rabies vaccination campaigns in the wake of the pandemic.

These data would also benefit agencies such as USDA's Animal and Plant Health Inspection Service (APHIS), which have an interest in regulating dog imports with the intent of reducing the risk of introduction of diseases that may affect U.S. livestock. For example, in 2021, APHIS issued a Federal Order²⁸ that established additional post-entry requirements on dogs for resale imported from countries with ongoing African swine fever transmission, which poses a significant risk to U.S. pork producers.²⁹ The potential economic benefits of reducing the risk of the importation of African swine fever could be significant; in fact, a recent outbreak in China in

²⁷ A Kunkel, Jeon S, Haim, Dilius CJP, Crowdis K, Meltzer MI, Wallace R (2021) The urgency of resuming disrupted dog rabies vaccination campaigns: a modeling and cost-effectiveness analysis. *Scientific Reports* (2021) 11:12476. <https://doi.org/10.1038/s41598-021-92067-5>.

²⁸ USDA/APHIS (2021) Federal Order for Importation of Live Dogs for Resale from Regions Where African Swine Fever Exists or is Reasonably Believed to Exist. https://www.aphis.usda.gov/import_export/downloads/vs-federal-order-asf.pdf and https://www.aphis.usda.gov/aphis/newsroom/news/sa_by_date/sa-2021/asf-dog-imports. Accessed June 5, 2023.

²⁹ Animal and Plant Health Inspection Service (Aug. 4, 2021) USDA Announces Requirements for Importing Dogs from Countries Affected with African Swine Fever. https://www.aphis.usda.gov/aphis/newsroom/news/sa_by_date/sa-2021/asf-dog-imports. Accessed: February 5, 2022.

2019 was estimated to have total economic losses equivalent to 0.78 percent of China's gross domestic product.³⁰ Thus, some of the requirements in this NPRM (if finalized as proposed) may mitigate the risks of introduction and transmission of diseases that impact livestock in addition to reducing the risk of dogs being imported while infected with DMRVV.

II. Public Participation

Interested persons or organizations are invited to participate in this proposed rulemaking by submitting written views, recommendations, and data on all aspects of the proposed rule notice. Comments received should reference a specific portion of the notice. Attachments and other supporting materials are part of the public record and subject to public disclosure. Submitters should not include any information in their comments or supporting materials that they consider confidential or inappropriate for public disclosure. HHS/CDC welcome comments on all aspects of this proposed rule, including the use of any forms or information collected and whether proposed requirements should be modified in any way.

HHS/CDC will carefully review, consider, and address all comments submitted and may revise the content of the rule as appropriate at the final rulemaking stage. HHS/CDC will publish a final rule after the comment period that reflects any content changes made because of comments received.

III. Background

A. Legal Authority

HHS/CDC has reviewed this rule under Executive Order 12988 on Civil Justice Reform and determines that this proposed rule meets the standard in the Executive Order. In this action, HHS/CDC proposes to revise 42 CFR 71.50 and 71.51.

³⁰ Shibing You, Tingyi Liu, Miao Zhang, Xue Zhao, Yizhe Dong, Bi Wu, Yanzhen Wang, Juan Li, Xinjie Wei and Baofeng Shi (2021). African swine fever outbreaks in China led to gross domestic product and economic losses. *Nature Food*; 2: 802–808.

The primary legal authority supporting this proposed rulemaking is section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264). Under section 361, the Secretary of HHS (Secretary) may make and enforce such regulations as in the Secretary's judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States and from one State or possession into any other State or possession.³¹ It also authorizes the Secretary to promulgate and enforce a variety of public health regulations to prevent the spread of communicable diseases, including through inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be sources of dangerous infection to human beings, and other measures. Since at least 1956, Federal quarantine regulations (currently found at 42 CFR 71.51) have controlled the entry of dogs and cats into the United States.³²

In addition to section 361, other sections of the PHS Act relevant to this proposed rulemaking are section 362 (42 U.S.C. 265), section 365 (42 U.S.C. 268), section 367 (42 U.S.C. 270), and section 368 (42 U.S.C. 271). Section 362, among other things, authorizes the Secretary to promulgate regulations prohibiting, in whole or in part, the introduction of property from foreign countries or places, for such period of time and as necessary for such purpose, to avert the serious danger of introducing communicable disease into the United States. Section 365 provides that it shall be the duty of customs officers and of Coast Guard officers to aid in the enforcement of quarantine rules and regulations.³³ Through this statutory provision, CBP

³¹ Although the statute assigns authority to the Surgeon General, all statutory powers and functions of the Surgeon General were transferred to the Secretary of HHS in 1966, 31 Fed. Reg. 8855, 80 Stat. 1610 (June 25, 1966), *see also* Pub. L. No. 96-88, § 509(b), October 17, 1979, 93 Stat. 695 (codified at 20 U.S.C. 3508(b)). The Secretary has retained these authorities despite the reestablishment of the Office of the Surgeon General in 1987.

³² *See* 21 Fed. Reg. 9870 (Dec. 12, 1956).

³³ 42 U.S.C. 268(b). The terms "officer of the customs" and "customs officer" are defined by statute to mean, "any officer of the United States Customs Service of the Treasury Department (also hereinafter referred to as the "Customs Service") or any commissioned, warrant, or petty officer of the Coast Guard, or any agent or other person, including foreign law enforcement officers, authorized by law or designated by the Secretary of the Treasury to perform any duties of an officer of the Customs Service." 19 U.S.C. 1401(i). Although this provision refers to the Secretary of the Treasury, the Homeland Security Act transferred to the Secretary of Homeland Security all "the functions, personnel, assets, and liabilities of . . . the United States Customs Service of the Department of the Treasury, including the functions of the Secretary of the Treasury relating thereto . . . [,]" 6 U.S.C. 203(1), such that reference to the Secretary of the Treasury should be read to reference the Secretary of Homeland Security.

provides critical assistance in enforcing Federal quarantine regulations at U.S. ports. Section 367 (42 U.S.C. 270) also authorizes the application of certain sections of the PHS Act to air navigation and aircraft to such extent and upon such conditions as deemed necessary for safeguarding public health and authorizes the promulgation of regulations, including provisions for penalties and forfeitures for violations.

Section 368 of the PHS Act provides that any person who violates regulations implementing sections 361 or 362 is subject to imprisonment of not more than one year, a fine, or both. Pursuant to 18 U.S.C. 3559 and 3571, an individual may face a fine of up to \$100,000 for a violation not resulting in death and up to \$250,000 for a violation resulting in death. Under section 368, HHS/CDC may refer violators to the U.S. Department of Justice for criminal prosecution. HHS/CDC does not have independent authority under section 368 to impose criminal fines or imprison violators.

Through this NPRM, HHS/CDC proposes new language advising individuals and organizations that it may request that DHS/CBP take additional action pursuant to 19 U.S.C. 1592 and 19 U.S.C. 1595a. Specifically, CDC may request that DHS/CBP issue additional fines, citations, or penalties to importers or carriers whenever the CDC Director (Director) has reason to believe that an importer or carrier has violated any of the provisions of this section or otherwise engaged in conduct contrary to law. HHS/CDC stresses that it does not administer Title 19, and decisions regarding whether to issue such fines, citations, or other penalties would be entirely at the discretion of DHS/CBP and subject to its policies and procedures. Notwithstanding, HHS/CDC believes it important to include this language to advise individuals and organizations that it may request that DHS/CBP pursue such actions.

Through this NPRM, HHS/CDC further clarifies that there is no agency policy of using the “least restrictive means” (as that concept is typically understood and applied in cases involving interests protected by the U.S. Constitution) in regard to animal importations under 42 CFR part 71. “The Due Process Clause of the Fourteenth Amendment imposes procedural

constraints on governmental decisions that deprive individuals of liberty or property interests.” *Nozzi v. Hous. Auth. of City of Los Angeles*, 806 F.3d 1178, 1190 (9th Cir. 2015). However, “[d]ue process protections extend only to deprivations of protected interests.” *Shinault v. Hawks*, 782 F.3d 1053, 1057 (9th Cir. 2015). Because individuals have no protected property or liberty interest in importing dogs or other animals into the United States, it is HHS/CDC’s policy to not employ a constitutional analysis of “least restrictive means” in regard to animal imports under 42 CFR part 71. *See Ganadera Ind. V. Block*, 727 F.2d 1156, 1160 (D.C. Cir. 1984) (“no constitutionally-protected right to import into the United States”); *see also Arjay Assoc. v. Bush*, 891 F.2d. 894, 896 (Fed. Cir. 1989) (“It is beyond cavil that no one has a constitutional right to conduct foreign commerce in products excluded by Congress.”). Members of the public are invited to comment regarding this clarification to HHS/CDC’s animal import policy.

B. Historical Background

Rabies is one of the deadliest zoonotic diseases and accounts for an estimated 59,000 human deaths globally each year.³⁴ Over 98 percent of those deaths are due to DMRVV.³⁵ The rabies virus can infect any mammal and, once clinical signs appear, the disease is almost always fatal.³⁶ In September 2007, at the Inaugural World Rabies Day Symposium, HHS/CDC declared the United States to be free of DMRVV.³⁷ While bat rabies lyssaviruses and multiple terrestrial variants of rabies continue circulating in wildlife species (e.g., fox, raccoon, and skunk) in the United States, the country has been free of DMRVV since 2007 and focuses its regulatory efforts on preventing the reintroduction of this rabies virus variant. The close relationship between dogs

³⁴ World Health Organization (2018). *WHO Expert Consultation on Rabies* (WHO Technical Report Series 1012). Retrieved from <https://www.who.int/publications/i/item/WHO-TRS-1012>.

³⁵ Hampson K, Coudeville L, Lembo T, et al.; Global Alliance for Rabies Control Partners for Rabies Prevention. Estimating the global burden of endemic canine rabies. *PLoS Negl Trop Dis* 2015;9:e0003709. <https://doi.org/10.1371/journal.pntd.0003709>.

³⁶ Fooks, A. R., Banyard, A.C., Horton, D.L., Johnson, N., McElhinney, L.M., and Jackson, A.C. (2014) Current status of rabies and prospects for elimination. *Lancet*, 384(9951), 1389-1399. doi: 10.1016/S0140-6736(13)62707-5.

³⁷ Velasco-Villa, A., Mauldin, M., Shi, M., Escobar, L., Gallardo-Romero, N., Damon, I., Emerson, G. (2017) The history of rabies in the Western Hemisphere. *Antiviral Res*, 146, 221-232. doi:10.1016/j.antiviral.2017.03.013.

and people means there is a direct public health risk to individuals that interact with inadequately vaccinated dogs imported from countries at high risk of DMRVV. One of CDC's principal goals is to prevent the reintroduction and spread of DMRVV in the United States.

DMRVV is still a serious public health threat in the more than 100 countries where it remains enzootic.³⁸ DMRVV has been highly successful at adapting to new host species, particularly wildlife, that can further transmit the virus.³⁹ Although the U.S. Government does not precisely track the total number of dogs imported each year, CDC previously estimated that approximately 1 million dogs are imported into the United States annually, of which 100,000 dogs are from DMRVV high-risk countries.⁴⁰ This estimate was based on information provided by airlines, CBP, and a public health study conducted at a U.S.-Mexico land border crossing.⁴¹

Preventing the entry of animals infected with DMRVV into the United States is a public health priority. When it is discovered that a rabid dog has been imported into the United States, a multi-agency response is required. This can involve CDC, USDA, CBP, State and local health departments and animal health officials, and veterinarians in the local community. Local, State, and Federal government agencies primarily incur the costs of investigation, testing, and response efforts. Since 2015 there have been four known rabid dogs imported into the United States. Each of the dogs was imported by a different animal rescue organization for the purposes of U.S. adoption. These four cases, discussed in detail below, highlight the vast amount of public health resources that are required to investigate, respond to, and mitigate the public health threat posed by the importation of a rabid dog.

³⁸ Hampson K, Coudeville L, Lembo T, et al.; Global Alliance for Rabies Control Partners for Rabies Prevention. Estimating the global burden of endemic canine rabies. *PLoS Negl Trop Dis* 2015;9:e0003709. <https://doi.org/10.1371/journal.pntd.0003709>.

³⁹ Velasco-Villa A, Mauldin MR, Shi M, et al. The history of rabies in the Western Hemisphere. *Antiviral Res.* 2017;146:221-232. doi:10.1016/j.antiviral.2017.03.013.

⁴⁰ HHS/CDC. Guidance Regarding Agency Interpretation of "Rabies-Free" as It Relates to the Importation of Dogs Into the United States. 84 Fed. Reg. 724,724-730 (Jan. 31, 2019).

⁴¹ McQuiston, J.H., et al., Importation of dogs into the United States: risks from rabies and other zoonotic diseases. *Zoonoses Public Health*, 2008. 55(8-10): p. 421-6.

In 2015, a rabid dog was part of a group of eight dogs and 27 cats imported from Egypt by an animal rescue group. The dog had an unhealed leg fracture and began showing signs of rabies four days after arrival. Following the DMRVV diagnosis, animal rescue workers in Egypt admitted that the dog's rabies vaccination documentation had been intentionally falsified to evade CDC entry requirements.⁴² As a result of this single importation, public health officials recommended that 18 people receive rabies PEP, seven dogs underwent a six-month quarantine, and eight additional dogs housed in the same home as the rabid dog had to receive rabies booster vaccinations and undergo a 45-day monitoring period.⁴³

In 2017, a flight parent imported four dogs from Egypt on behalf of an animal rescue organization. One of the dogs appeared agitated and bit the flight parent prior to the flight. A U.S. veterinarian examined the dog one day after its arrival and then euthanized and tested the dog for rabies. A post-mortem rabies test showed that the dog was positive for DMRVV.⁴⁴ Public health officials recommended that at least four people receive rabies PEP, and the remaining three dogs underwent quarantine periods ranging from 30 days to six months. An investigation revealed the possibility of falsified rabies vaccination documentation presented on entry to the United States.⁴⁵

Another example in 2019 involved 26 dogs that were imported into the United States from Egypt by a rescue organization. All dogs had rabies vaccination documentation and serologic documentation indicating the presence of rabies antibodies in response to immunization, based on results from an Egyptian government-affiliated rabies laboratory.

⁴² Sinclair JR, Wallace RM, Gruszynski K, et al. Rabies in a dog imported from Egypt with a falsified rabies vaccination certificate—Virginia, 2015. *MMWR Morb Mort Wkly Rep* 2015;64:1359–62. <https://doi.org/10.15585/mmwr.mm6449a2>.

⁴³ Quarantine periods for animals exposed to rabies can vary between 30 days to six months based on several factors, including vaccination history, serologic titers or prospective serologic monitoring results, or jurisdictional requirements.

⁴⁴ The diagnosis of rabies requires laboratory confirmation on the basis of a positive result for the direct fluorescent antibody test performed on CNS tissue collected post-mortem. National Association of State Public Health Veterinarians. Compendium of animal rabies prevention and control, 2016. *JAVMA* 2016; 248 (5):505-517.

⁴⁵ Hercules Y, Bryant NJ, Wallace RM, et al. Rabies in a dog imported from Egypt—Connecticut, 2017. *MMWR Morb Mort Wkly Rep* 2018;67:1388–91. <https://doi.org/10.15585/mmwr.mm6750a3>.

However, one dog developed signs of rabies three weeks after arrival and, when euthanized, tested positive for DMRVV. The resulting public health investigation raised suspicions that the rabies vaccination documents and serological test results were falsified for all 26 dogs in the shipment because 18 dogs in the shipment lacked serologic evidence of vaccination when re-tested in the United States. Due to this event, 44 people were required to receive PEP and the 25 other dogs imported on the same flight underwent re-vaccination and quarantines that ranged from four to six months. The rabid dog had been released into an individual's home because of its false paperwork and subsequently had contact with an additional 12 dogs, all of which had to be revaccinated and undergo quarantine periods ranging from 45 days to six months.⁴⁶ The public health investigations and administration of rabies PEP to exposed persons in this case cost more than \$400,000 in state resources.^{47, 48} As a result of the rabid dog importations that occurred in 2015, 2017, and 2019, CDC issued a temporary suspension for dogs entering the United States from Egypt.^{49,50}

In June 2021, 33 dogs and one cat were imported into the United States from Azerbaijan by an animal rescue organization. All dogs had rabies vaccination documents that appeared valid upon arrival in the United States. Three days after arrival, one dog developed signs of rabies and was euthanized. CDC confirmed the dog was infected with DMRVV known to circulate in the Caucasus Mountains region of Azerbaijan. The remaining rescue animals exposed to the rabid dog during travel were quickly dispersed across nine states, leading to what is believed to be the

⁴⁶ Raybern, C et al. Rabies in a dog imported from Egypt-Kansas, 2019. *MMWR Morb Mort Wkly Rep* 2020; 69 (38): 1374-1377.

⁴⁷ *Id.*

⁴⁸ Centers for Disease Control and Prevention (2022). Rabies Postexposure Prophylaxis. Retrieved from https://www.cdc.gov/rabies/medical_care/index.html.

⁴⁹ 84 Fed. Reg. 20628 (May 10, 2019).

⁵⁰ CDC implemented this suspension because of the lack of veterinary controls available in Egypt to prevent the exportation of rabid dogs. With limited exceptions, CDC began requiring a *CDC Dog Import Permit* and documentation of the dog's rabies serologic tests from World Organisation for Animal Health (WOAH)-approved laboratories for eligible importers. Since these permit and serologic test requirements were implemented, no rabid dogs have been imported from Egypt.

largest, multi-state, imported rabid dog investigation in U.S. history.⁵¹ Eighteen people received PEP to prevent rabies because of exposure to the rabid dog. CDC performed the test known as the “Prospective Serologic Monitoring” test on the remaining dogs and the public health investigation revealed that improper vaccination practices by the veterinarian in Azerbaijan likely contributed to the inadequate vaccination response documented in 48 percent of the imported animals, including the rabid dog.⁵² The 33 exposed animals were revaccinated and placed in quarantine for periods ranging from 45 days to six months.⁵³

CDC estimates a range of costs for public health investigations and subsequent cost of care for people exposed to rabid dogs to be between \$220,00 and \$520,000 per importation event, as summarized in Section VI.^{54, 55} This cost estimate does not include the cost to evaluate, vaccinate, test, and quarantine exposed animals. This cost estimate also does not account for the worst-case outcomes, which include: (1) transmission of rabies to a person who dies from the disease; and (2) ongoing transmission to other domestic and wildlife species in the United States.

DMRVV becoming re-established in the United States would result in costly efforts over several years to eliminate the virus again. The extraordinary cost of re-introduction of DMRVV is demonstrated by an instance of reintroduction that occurred in Texas, where DMRVV had been previously eliminated. The reintroduction resulted in several human deaths; the subsequent

⁵¹ Whitehill F, Bonaparte S, Hartloge C, et al. Rabies in a Dog Imported from Azerbaijan- Pennsylvania, 2021. *MMWR Morb Mortal Wkly Rep* 2022; 71: 686-689.

⁵² Centers for Disease Control and Prevention (2021). CDC responds to a case of rabies in an imported dog. Retrieved from <https://www.cdc.gov/worldrabiesday/disease-detectives/rabies-imported-dog.html>.

⁵³ Whitehill F, Bonaparte S, Hartloge C, et al. Rabies in a Dog Imported from Azerbaijan- Pennsylvania, 2021. *MMWR Morb Mort Wkly Rep* 2022; 71: 686-689.

⁵⁴ Raybern, C et al. Rabies in a dog imported from Egypt-Kansas, 2019. *MMWR Morb Mort Wkly Rep* 2020; 69 (38): 1374-1377.

⁵⁵ CDC. Guidance Regarding Agency Interpretation of “Rabies-Free” as It Relates to the Importation of Dogs Into the United States. 84 Fed. Reg. 724 (Jan. 31, 2019).

re-elimination of DMRVV cost \$60 million (in 2022 USD) and required over 10 years of effort.^{56, 57}

Historically, approximately 60 to 70 percent of CDC's dog entry denials (or about 200 cases annually) have been based on fraudulent, incomplete, or inaccurate paperwork.⁵⁸ However, between January 2020 and July 2021 (i.e., during the COVID-19 pandemic, prior to the temporary suspension), CDC documented more than 1000 instances of incomplete, inadequate, or fraudulent rabies vaccination certificates for dogs arriving from DMRVV high-risk countries.⁵⁹ These cases resulted in dogs being denied entry into the United States and ultimately returned to their country of origin.

The significant increase in the number of dogs from DMRVV high-risk countries arriving with incomplete, inadequate, or fraudulent rabies vaccination documentation observed in 2020 and 2021 coincided with increased interest in purchasing dogs from the international rescues and breeders during the COVID-19 pandemic.^{60, 61, 62} Since 2021, the demand for puppies and rescue dogs has remained high. The trend in purchasing and rescuing dogs from abroad has been noted in many countries, including the United States.^{63, 64, 65, 66} Internationally, there has been

⁵⁶ Thomas, S., Wilson, P., Moore, G., Oertli, E., Hicks, B., Rohde, R., Johnston, D. (2005). Evaluation of oral rabies vaccination programs for control of rabies epizootics in coyotes and gray foxes: 1995-2003. *Journal of the American Veterinary Medicine Association*, 227(5),785-92. doi: 10.2460/javma.2005.227.785.

⁵⁷ Sterner, R., Meltzer, M., Shwiff, S., Slate, D. (2009). Tactics and Economics of Wildlife Oral Rabies Vaccination, Canada and the United States. *Emerging Infectious Diseases*, 15(8), 1176-1184. doi: 10.3201/eid1508.081061.

⁵⁸ Centers for Disease Control and Prevention (2021). Quarantine Activity Reporting System (version 4.9.8.8.2.2A). Dog Importation data, 2010-2019. Accessed 1 October 2022.

⁵⁹ Pieracci, E., Williams, C., Wallace, R., Kalapura, C., Brown, C. U.S. dog importations during the COVID-19 pandemic: Do we have an erupting problem? *PLoS ONE*,16(9), e0254287. doi: 10.1371/journal.pone.0254287.

⁶⁰ *Id.*

⁶¹ Wynne E. Dog lovers find prices rise steeply amid COVID-fueled demand. *Australian Broadcasting Corporation News*. May 20, 2021.

⁶² Morgan L, Protopopova A, Birkler RID, Itin-Shwatz B, Sutton G, Gamliel A, et al. Human-dog relationships during the COVID-19 pandemic: booming dog adoption during social isolation. *Humanities and Social Science Communications*. 2021; 7(150): 1-11.

⁶³ Pieracci, E., Williams, C., Wallace, R., Kalapura, C., Brown, C. U.S. dog importations during the COVID-19 pandemic: Do we have an erupting problem? *PLoS ONE*,16(9), e0254287. doi: 10.1371/journal.pone.0254287.

⁶⁴ Wynne E. Dog lovers find prices rise steeply amid COVID-fueled demand. *Australian Broadcasting Corporation News*. May 20, 2021.

⁶⁵ Morgan L, Protopopova A, Birkler RID, Itin-Shwatz B, Sutton G, Gamliel A, et al. Human-dog relationships during the COVID-19 pandemic: booming dog adoption during social isolation. *Humanities and Social Science Communications*. 2021; 7(150): 1-11.

⁶⁶ Velez M. I adopted my dog Cannoli from overseas. It's easier than you think. 9/20/2020. Available at: <https://www.thedailybeast.com/i-adopted-my-dog-cannoli-from-overseas-its-easier-than-you-think>.

significant growth within the companion animal breeding industry with increasing international trade.⁶⁷ Multiple international and U.S. investigations have identified importations of puppies that were too young to meet rabies vaccination requirements.^{68, 69, 70, 71} In addition, there is growing evidence that criminal networks are becoming involved in the lucrative dog trade, and the illegal puppy trade was reported to have increased during the pandemic.^{72, 73, 74} Because imported dogs will typically encounter multiple people, pets, and other animals throughout their journey—beginning at the airport in the country of departure and continuing with the airline, through the U.S. port, and pet adoption and pet socialization process—an increase in inadequately vaccinated dogs likewise increases the risk of human and animal exposure.⁷⁵

Temporary Suspension of the Importation of Dogs from DMRVV High-Risk Countries

In light of these concerns, on June 16, 2021, CDC announced a temporary suspension of the importation of dogs from DMRVV high-risk countries to protect the public's health. The temporary suspension was issued because public health resources were being diverted to the response to the COVID-19 pandemic, which limited the availability of resources to respond to dog importation issues. This diversion of resources coincided with the documented increase in

⁶⁷ Maher J, Wyatt T. European illegal puppy trade and organized crime. *Trends in Organized Crime*. 2021; 24(4) 506-525.

⁶⁸ Pieracci, E., Williams, C., Wallace, R., Kalapura, C., Brown, C. U.S. dog importations during the COVID-19 pandemic: Do we have an erupting problem? *PLoS ONE*, 16(9), e0254287. doi: 10.1371/journal.pone.0254287.

⁶⁹ Zucca P, Rossman MC, Osorio JE, Kareem K, De Benedictis P, Haifsl J, et al. The 'bio-crime model' of cross-border cooperation among veterinary public health, justice, law enforcements, and customs to tackle the illegal animal trade/bio-terrorism and to prevent the spread of zoonotic diseases among human population. *Frontiers in Veterinary Science*. 2020; 7: 1-13.

⁷⁰ Cocchi M, Danesi P, DeZan G, Leati M, Gagliazzo L, et al. A three-year biocrime sanitary surveillance on illegally imported companion animals. *Pathogens*. 2021; 10(80):1-12.

⁷¹ Houle MK. Perspective from the field: Illegal puppy imports uncovered at JFK airport. 2017. Available at: www.cdc.gov/nczid/dgmq/feature-stories/operation-dog-catcher.html.

⁷² Maher J, Wyatt T. Rural-urban dynamics in the UK illegal puppy trade: trafficking and trade in man's best friend. *International Journal of Rural Law and Policy*. 2019; 9 (2): 1-20.

⁷³ Zucca P, Rossman MC, Osorio JE, Kareem K, De Benedictis P, Haifsl J, et al. The 'bio-crime model' of cross-border cooperation among veterinary public health, justice, law enforcements, and customs to tackle the illegal animal trade/bio-terrorism and to prevent the spread of zoonotic diseases among human population. *Frontiers in Veterinary Science*. 2020; 7: 1-13.

⁷⁴ British Broadcasting Corporation. Illegal puppy trade warning as sales boom during the COVID pandemic. 18 NOV 2020. *British Broadcasting Corporation News*.

⁷⁵ Centers for Disease Control and Prevention. Quarantine Activity Reporting System (version 4.9.8.8.2.2A). Dog importation data, 2018-2020. Accessed: February 15, 2021.

fraudulent vaccine documentation and importers circumventing dog import regulations. To address these concerns, CDC developed a framework for dog importation requiring importers to apply for special permission to import a dog into the United States. Importers were required to submit an *Application for Special Exemption for a Permitted Dog Import* form⁷⁶ and obtain a *CDC Dog Import Permit* prior to importing a dog into the United States. To obtain a permit, an importer had to demonstrate that the dog was at least six months old, had a microchip, had proof of rabies vaccination, and had obtained a serologic titer test from a CDC-approved laboratory if the dog was vaccinated outside the United States.

From July 14, 2021, to June 9, 2022, CDC issued *CDC Dog Import Permits* on a limited basis, for persons permanently relocating to the United States, importers of government-owned working dogs, or owners of service animals⁷⁷ to alleviate the potential burden of the temporary suspension for these categories of importers. On December 1, 2021, consistent with public health standards of practice, CDC eased some of the temporary suspension restrictions. CDC allowed dogs six months of age or older that were microchipped and accompanied by valid U.S. RVCs to re-enter the United States without a *CDC Dog Import Permit*. Because these dogs were vaccinated in the United States, CDC determined that allowing them to enter without a *CDC Dog Import Permit* would be unlikely to endanger the public's health. To provide additional resources for importers of foreign-vaccinated dogs, CDC expanded the number of approved rabies serologic testing laboratories from five to 60 laboratories.⁷⁸ CDC also reduced the wait time following collection of a serologic sample to permit dogs to be eligible to enter the United States after only 45 days, rather than the previous 90-day waiting period. In addition, based on data from the latter part of 2021 showing a significant decrease in the arrival of ill dogs and dogs

⁷⁶ Approved under OMB Control Number 0920-1383 Importation Regulations (42 CFR 71 Subpart F) (exp. 1/31/2026, or as revised).

⁷⁷ A service dog must meet the definition of a "service animal" under 14 CFR 382.3, be accompanied by an "individual with a disability" as defined under 14 CFR 382.3, and work or perform tasks directly related to that individual's disability.

⁷⁸ List of CDC-approved labs can be found at www.cdc.gov/importation/bringing-an-animal-into-the-United-States/approved-labs.html.

being denied entry, CDC allowed imported dogs from DMRVV high-risk countries to enter through any of the 18 U.S. airports with a CDC quarantine station.^{79, 80}

Even with the temporary suspension in place, CDC documented multiple instances of importers attempting to circumvent entry requirements by using fraudulent rabies vaccination documents that had been fabricated to make them appear as if they had been issued in the United States. CDC also documented instances of importers presenting fraudulent rabies vaccination documents purporting to be from DMRVV-free countries to import young puppies from DMRVV high-risk countries into the United States, presumably for resale. These factors highlight the need for rabies vaccination documentation to be standardized for all dogs arriving from DMRVV high-risk countries to reduce the likelihood of falsified documentation in the future.

On June 1, 2022, CDC announced that effective June 10, 2022, it would modify and extend the temporary suspension through January 31, 2023.⁸¹ The suspension was extended based on the continued risk of the reintroduction of DMRVV into the United States and the ongoing need to commit global public health resources towards the COVID-19 pandemic. Between the temporary suspension going into effect on July 14, 2021, and June 1, 2022, CDC documented a decrease in dog importation issues that existed prior to the suspension (e.g., the number of suspected fraudulent rabies vaccination documents, the number of dogs that were sick or dead upon arrival). CDC's ability to track and monitor dog imports from DMRVV high-risk countries also improved during this timeframe. For these reasons, CDC modified the terms of the temporary suspension to allow more dog imports into the United States by a wider range of

⁷⁹ List of U.S. ports with a CDC quarantine station available at: www.cdc.gov/quarantine/quarantinestationcontactlistfull.html.

⁸⁰ At the time the Federal Register announcing the temporary suspension was published, dogs imported from high-risk countries were only allowed to enter the United States through the one port of entry with an animal care facility. However, CDC's review of dog importation data from July 14 - November 30, 2021, noted a significant decrease in the arrival of ill dogs and dogs denied entry, reducing the need for dogs to enter only through U.S. ports with an animal care facility.

⁸¹ Notice of Extension and Modification of Temporary Suspension of Dogs Entering the United States From High-Risk Rabies Countries. 87 Fed. Reg. 33158 (June 1, 2022).

importers building upon the requirements that had already been in place and had been successful in reducing dog importation issues. On February 1, 2023, CDC extended the temporary suspension without modifications through July 31, 2023, because of a continued risk of reintroduction of DMRVV due to insufficient veterinary controls in DMRVV high-risk countries to prevent the export of inadequately vaccinated dogs and veterinary supply chain and workforce capacity shortages that have persisted since the global COVID-19 pandemic.⁸²

In parallel with the publication of this NPRM, CDC has published an extension of the temporary suspension through July 31, 2024. A suspension remains necessary to protect the public's health against the reintroduction of DMRVV into the United States because there is a continued threat posed by dogs from high-risk countries that are unvaccinated or inadequately vaccinated against rabies. This continued threat is due to various factors, including: a high volume of dogs being imported into the United States contemporaneous with insufficient veterinary controls in high-risk countries to prevent the export of inadequately vaccinated dogs, inadequate veterinary supply chains for vaccines and related materials, and persistent workforce capacity shortages, particularly in high-risk countries that export dogs to the United States. Through this NPRM, HHS/CDC proposes to address the various concerns with the importation of dogs observed in recent years by establishing a regulatory framework based on the documented successes of the temporary suspension. In addition, the requirements and standards proposed in the rule would help ensure the health and safety of imported animals while also protecting the public's health and preventing the reintroduction of DMRVV into the United States.

There are numerous challenges associated with reviewing rabies vaccination documentation from around the world, including the lack of a standardized rabies vaccination documents, different required elements on a rabies vaccination documents, differences in who

⁸² 88 Fed. Reg. 5348 (Jan. 27, 2023).

can vaccinate and issue rabies vaccination documents, and limited to no accountability for unlicensed or unauthorized vaccinators. CDC has documented numerous instances of fraudulent or erroneous paperwork for dogs based on various factors. These include:

- Dogs that were younger than the age indicated on their rabies vaccination paperwork (based on dental examination by U.S. veterinarians);
- Differences between the breed, sex, color, or microchip number listed on the rabies vaccination documents and the dog presented for admission;
- Suspicious veterinary stamps and inconsistent signatures across veterinary paperwork;
- Inconsistent dates of rabies vaccination between different veterinary documents; and
- Vaccines administered after the expiration date of the vaccine lot.

The international public health community has recognized that rabies vaccination documentation alone is no longer sufficient to ensure adequate protection against rabies.^{83, 84} Numerous DMRVV-free countries, including Australia, New Zealand, and European Union member states, already require a two-step verification of rabies vaccination status for dogs imported from DMRVV high-risk countries (when direct importation is allowed), by which a valid RVC and proof of adequate rabies serologic test are required for importation. The international standard is to capture any required information for movement of animals via an “import (movement) certificate.” Import certificates can be standardized, which helps to ensure all required information is included and the information is verified by an Official Government Veterinarian in the exporting country prior to the animal’s shipment to the United States. Implementing the use of standardized import certificates, which have long been used for the international movement of animals and are well understood by foreign governments, would

⁸³ World Organisation for Animal Health. Terrestrial Code Online Access - WOA - World Organisation for Animal Health, Chapter 2.1.17 and 8.14. https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre_certif_rabies.htm.

⁸⁴ World Health Organization. Expert Consultation on Rabies, Third Report. Geneva, Switzerland. 2018.

enhance compliance with CDC entry requirements and ensure that follow-up with the exporting country can occur if import violations are noted.⁸⁵

In addition to issues with fraudulent or incomplete rabies vaccination documents, CDC has observed in recent years a number of practices that raised concerns relating to how airlines transport and house animals. Some airlines have chosen to leave dogs denied admission or pending determination of admissibility in cargo warehouses, which can create an unsafe environment for workers exposed to dogs with zoonotic diseases (such as rabies, brucellosis, leptospirosis, and numerous intestinal or external parasites). Workers also risk bites, scratches, and other injuries, as they are not trained to handle live animals and are required to feed, water, and provide breaks or cage cleaning for the animals in accordance with USDA Animal Welfare Act standards. As a result, many animals are left in crates for extended periods of time without immediate supervision while warehouse workers conduct routine duties. These conditions are often unsafe for dogs due to the prolonged periods of time between flights, inadequate cooling and heating, non-compliant cleaning and sanitization of crates, and the inability to physically separate the animals from areas of the warehouse where other equipment, machinery, and goods are used and stored.

CDC has documented numerous instances of dogs housed under inadequate conditions while in the care of airlines. For example, during the COVID-19 pandemic, fewer international flights worldwide^{86, 87} resulted in delayed returns for dogs denied admission to the United States. In August 2020, a dog died in the custody of an airline at Chicago O'Hare International Airport after CDC denied admission to a group of dogs based on falsified rabies vaccination documentation. Despite CDC's request to find appropriate housing at a local kennel or veterinary

⁸⁵ https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/iregs-for-animal-exports/ct_iregs_animal_exports_home.

⁸⁶ <https://www.cnn.com/2020/04/02/coronavirus-update-american-airlines-cuts-summer-international-flights-by-60percent-as-demand-suffers.html>.

⁸⁷ <https://news.aa.com/news/news-details/2020/American-Airlines-Announces-Additional-Schedule-Changes-in-Response-to-Customer-Demand-Related-to-COVID-19-031420-OPS-DIS-03/default.aspx>.

clinic, the airline left 18 dogs in a cargo warehouse without food and water for more than 48 hours contributing to the death of one dog.⁸⁸ In March 2023, a dog arrived at a U.S airport without a CDC-registered Animal Care Facility. The dog was later found dead in the airline's cargo warehouse.⁸⁹

Because there are insufficient numbers of animal care facilities with a USDA intermediate handlers license and a CBP-issued FIRMS code available to house dogs that are denied admission, CDC worked with USDA, CBP, and local businesses to identify and approve five new animal care facilities in 2021 and 2022 as part of the strategic shift towards safer importation controls. As of June 1, 2023, there are five CDC-registered Animal Care Facilities with a USDA intermediate handlers license and a FIRMS code issued by CBP. The five facilities are located at Atlanta Hartsfield-Jackson International Airport, John F. Kennedy International Airport (New York), Los Angeles International Airport, Miami International Airport, and Washington Dulles International Airport (Washington DC Metropolitan Area).

While airlines are ultimately responsible for finding appropriate housing for dogs denied admission, the inadequate number of facilities with a CBP-issued FIRMS code and USDA intermediate handlers license for holding and providing care for live animals creates significant administrative and financial burdens for Federal, State, and local governments. To address these concerns, this NPRM proposes that if a CDC-registered Animal Care Facility with a CBP-issued FIRMS code and USDA intermediate handlers license is not available to hold a dog while the U.S. Government determines admissibility, the airline that has transported the dog would be required to, at a minimum, arrange transfer of the animal to a veterinary clinic or kennel that meets USDA Animal Welfare Act standards⁹⁰ and is approved by CDC.

⁸⁸ <https://www.cbsnews.com/chicago/news/dog-dies-at-ohare-airport-warehouse-17-others-saved-after-being-left-without-food-or-water-for-3-days/>.

⁸⁹ Centers for Disease Control and Prevention. Quarantine Activity Reporting System. March 2023.

⁹⁰ U.S. Department of Agriculture. Animal Welfare Regulations; Part 3, Subpart A: Transportation Standards. Sections 3.14-3.20. July 2020. Available at: https://www.aphis.usda.gov/animal_welfare/downloads/AC_BlueBook_AWA_508_comp_version.pdf.

While costs associated with housing, caring for dogs, and returning dogs are the responsibility of the importer (or airline if the importer abandons the dog), some importers and airlines have been reluctant to pay these costs, requiring the Federal government to find appropriate interim housing facilities, and veterinary care. The cost to house, care for, and return inadequately vaccinated dogs ranges between \$1,000 and \$4,000 per dog, depending on the location and time required until the next available return flight. The Federal government has been required to find individualized solutions to ensure appropriate accommodations for prolonged periods of time for these animals pending return to their countries of departure and has been left to bear the costs for such housing, care, and return of dogs when airlines and importers have not. The increasing demand to vaccinate and quarantine dogs that have been denied admission presents an increasing burden to Federal, State, and local public health agencies.^{91, 92} The increased need for inspections, veterinary medical care, and appropriate quarantine of dogs inadequately vaccinated against rabies has financially burdened Federal and State agencies while also putting the public's health at risk.

Additionally, an increasing number of dogs being imported do not meet age requirements of multiple agencies. CDC has noted that 61 percent (890/1463) of dogs denied admission and 46 percent of ill or dead dogs arriving in the United States from 2019 to 2021 were under six months of age. During the first six months of 2021, CDC investigated 35 instances of sick or dead puppies under six months of age. CDC has also documented an increase in fraudulent rabies vaccination documentation from importers claiming the dogs were over four months of age.⁹³ Many of these dogs were imported into the United States for resale or adoption. USDA requires any dog entering the United States for resale or adoption to be six months of age; however, many

⁹¹ Pieracci EG, Maskery B, Stauffer K, Gertz A, Brown C. Risk factors for death and illness in dogs imported into the United States, 2010-2018. *Transbound Emerg Dis* 2022. DOI: 10.1111/tbed.14510.

⁹² Pieracci EG, Williams CE, Wallace RM, Kalapura CR, Brown CM (2021) U.S. dog importations during the COVID-19 pandemic: Do we have an erupting problem? *PLoS ONE* 16(9): e0254287. <https://doi.org/10.1371/journal.pone.0254287>.

⁹³ Pieracci, EG; Williams, CE; Wallace, RM; Kalapura, CR; Brown CM. U.S. dog importations during the COVID-19 pandemic: Do we have an erupting problem? *PLoS ONE* 2021;16 (9): e0254287.

importers claim the animals as personal pets to avoid the age requirement because younger dogs may be sold for more money.⁹⁴ This has led to multiple instances where young puppies, some as young as six weeks of age, were transported in violation of the Animal Welfare Act, which requires dogs to be at least eight weeks of age to be eligible to fly, in an attempt to circumvent the entry requirements of multiple agencies. Updated and standardized vaccination information collection and minimum age requirements will help address these issues.

The requirements proposed in this NPRM, if adopted, would also help address public health concerns regarding sick or dead animals being imported to the United States. If an animal arrives in the United States and appears ill or is dead, a public health investigation is required to ensure the ill or dead animal does not present a public health threat. The overall health of an animal can play a significant role in whether it can maintain core body functions (i.e., body temperature regulation and glucose levels) during prolonged flights. Stressed, malnourished, and young animals are more likely to become ill and can transmit communicable diseases that can affect humans;^{95, 96} therefore, safety and welfare concerns for the transport of dogs have a public health impact that requires a degree of oversight from public health agencies to ensure human and animal health is protected.⁹⁷ Additionally, diagnostic testing or necropsy of ill or dead animals, respectively, is critical to understand the underlying cause of illness or death and ensure the animals do not pose a public health risk.

The creation of standards for CDC-registered Animal Care Facilities; the requirement that all foreign-vaccinated dogs be examined, vaccinated, and quarantined (when applicable) at one of these facilities prior to entry into the United States; and the prevention measures in this

⁹⁴ *Id.*

⁹⁵ Galanis E et al. Brucellosis and other diseases imported with dogs. *BCMJ* 2019; 61 (4): 177-190. Available at: <https://bcmj.org/bccdc/brucellosis-and-other-diseases-imported-dogs>.

⁹⁶ Denstedt E. *Echinococcus multilocularis* as an emerging public health threat in Canada: A knowledge synthesis and needs assessment. Accessed: 28 February 2019. Available at: www.nccch.ca/sites/default/files/Guelph-Denstedt-2017.pdf.

⁹⁷ Pieracci EG, Maskery B, Stauffer K, Gertz A, Brown C. Risk factors for death and illness in dogs imported into the United States, 2010-2018. *Transbound Emerg Dis* 2022. DOI: 10.1111/tbed.14510.

proposed rule will mitigate the need for future broadly applied suspensions and help ensure the health and safety of imported animals while also serving to protect public health and prevent the reintroduction of DMRVV into the United States.

C. Current Process

Currently, per regulation at 42 CFR 71.51(c), there is no standard form used to capture rabies vaccination information. However, importers must present valid RVCs which must include all of the following information to be valid:

- Identifies a dog on the basis of breed, sex, age, color, markings, and other identifying information.
- Specifies a date of rabies vaccination at least 30 days before the date of arrival of the dog at a U.S. port.
- Specifies a date of expiration which is after the date of arrival of the dog at a U.S. port. If no date of expiration is specified, then the date of vaccination shall be no more than 12 months before the date of arrival at a U.S. port.
- Bears the signature of a licensed veterinarian.

Upon the dog's arrival in the United States, Federal officials examine the RVC and ensure the description of the dog listed on the paperwork matches the dog presented. For a rabies vaccine to be effective, the dog must be at least 12 weeks (84 days) of age at the time of administration. A dog's initial vaccine must also be administered at least four weeks (28 days) before arrival in the United States.

Under HHS/CDC's regulatory authority, dogs arriving from DMRVV high-risk countries without appropriate RVCs are denied admission and returned to the country of departure on the next available flight.⁹⁸ CDC currently recommends that airlines house dogs awaiting return to

⁹⁸ Guidance Regarding Agency Interpretation of "Rabies-Free" as it Relates to the Importation of Dogs into the United States, 84 Fed. Reg. 724 (Jan. 31, 2019).

their country of departure at a USDA-accredited facility that meets the USDA's Animal Welfare Act standards during transit. However, these facilities are often cargo warehouses that are not equipped to house live animals for more than several hours.

The transportation, care, and payment for sick or dead animals are highly variable and depend on whether the animal is suspected of having rabies. Ideally, local veterinarians are consulted immediately to provide care for sick animals; however, importers and owners frequently refuse to pay for the care of sick animals resulting in confusion and delayed care for often critically ill animals. When owners have refused to pay for the care of their sick animals, the responsibility has been transferred to the airline that transported the animals into the United States, but some airlines have been reluctant to pay costs associated with the care and housing of animals. While State health departments and CDC will test blood samples free of charge when rabies is suspected, in some instances, CDC has been left to cover the costs of animal care.

HHS/CDC believes that clarifying the regulatory requirements delineating importer and carrier responsibilities would streamline the animal importation process and help ensure sick animals receive timely veterinary care upon arrival in the United States if needed. We welcome input from the public on all proposals contained herein.

IV. Summary of Proposed Changes

Proposed Changes to 71.50

Section 71.50(b) contains definitions applicable to animal importations under subpart F of 42 CFR part 71. The definitions contained in paragraph (b) are of general scientific applicability and thus would apply to different animal imports, not just dogs and cats. HHS/CDC proposes adding the following definitions to 42 CFR 71.50(b): Authorized Veterinarian, histopathology, in-transit shipments, microchip, necropsy, Official Government Veterinarian.

Authorized Veterinarian means an individual who has obtained both an advanced degree and valid license and is authorized to practice animal medicine in the exporting country.

Histopathology means the study of changes in animal tissue caused by disease.

In-Transit Shipment means a cargo shipment originating in a foreign country that is moved through one or more U.S. ports while transiting through the United States to a third-country destination.

Microchip means an implanted radio-frequency device placed under the skin of an animal that contains a unique identification tag that meets the International Standards Organization (ISO) compatibility through ISO 11784 or ISO 11785, or similar technologies as approved by the Director.

Necropsy means an animal autopsy in which the cause of death may be determined through the examination and collection of tissues, organs, or bodily fluids post-mortem.

Official Government Veterinarian means a veterinarian who performs work on behalf of an exporting country's government and can verify the license or credentials of an Authorized Veterinarian.

HHS/CDC also proposes adding a new subsection at 42 CFR 71.50(c) addressing the legal severability of provisions found in 42 CFR part 71 Subpart F – Importations. Because the provisions relating to importations under Subpart F are designed to protect the public's health from various zoonotic disease threats, HHS/CDC intends that these provisions have maximum legal effect. Accordingly, HHS/CDC proposes adding language that in the event any provision of this subpart is held by a reviewing court of law to be invalid or unenforceable by its terms, or as applied to any person or circumstance, that the provision be construed so as to continue to give the maximum effect to the provision permitted by law. If a reviewing court should hold that a provision is utterly invalid or unenforceable, then HHS/CDC intends that the provision be severable from Subpart F and not affect the remainder or the application of the provision to persons not similarly situated or to dissimilar circumstances. HHS/CDC seeks public comment regarding this and other proposed changes to 71.50.

Proposed Changes to 71.51

(a) Definitions.

Section 71.51(a) contains definitions specifically applicable to importations of dogs and cats under this section. Among other things, HHS/CDC proposes definitions for animal, CDC-registered Animal Care Facility, *CDC Import Submission Form*, conditional release, confinement, DMRVV-free countries, DMRVV high-risk countries, DMRVV low-risk countries, DMRVV-restricted countries, importer, SAFE TraQ, serologic testing, USDA-Accredited Veterinarian, and USDA Official Veterinarian. Some of these definitions were previously published in guidance.⁹⁹

Animal means all domestic cats (*Felis catus*) or domestic dogs (*Canis familiaris*).

CDC-registered Animal Care Facility means a facility registered by CDC for the purpose of providing veterinary care and housing to animals imported into the United States.

CDC Import Submission Form means an OMB-approved declaration¹⁰⁰ submitted to CDC through an online portal that includes the importer's name and contact information; description of the dog, including microchip number, current photographs of the dog's face and body; purpose of importation; travel information, including dates of departure and arrival, country of departure, countries visited in the past six months, and U.S. port of entry; and other information as described in CDC technical instructions. A receipt confirming successful submission of this form must accompany all dogs departing foreign locations for travel to the United States. For dogs departing from airports overseas with a U.S. final destination, the responsible airline must confirm the receipt prior to dogs being loaded onto departing aircraft.

Conditional release, when applied to a dog or cat, means the temporary release of a dog or cat from the custody of a carrier into the care of a licensed veterinarian approved by CDC for

⁹⁹ CDC. Guidance Regarding Agency Interpretation of "Rabies-Free" as It Relates to the Importation of Dogs Into the United States. 84 Fed. Reg. 724 (Jan. 31, 2019).

¹⁰⁰ Current OMB approval no. 0920-1383 (exp. 1/31/26).

the purpose of receiving emergency medical care or a public health evaluation, pending removal of the dog or cat from the United States. Dogs and cats must be returned immediately to the carrier's custody upon the conclusion of such medical care or evaluation for removal from the United States.

Confinement, when applied to a dog or cat, means restriction to a building or other enclosure at a U.S. port or other location approved by CDC, including *en route* to a destination, in isolation from other dogs and cats, and from persons except for contact necessary for its care. If the animal is allowed out of the enclosure, it must be muzzled and kept on a leash.

DMRVV-free countries means countries assessed by CDC based on internationally accepted standards as not having DMRVV present.

DMRVV low-risk countries means countries assessed by CDC as low risk for DMRVV transmission based on factors such as the virus being limited to a localized area, adequacy of surveillance and dog vaccination programs to prevent further geographic distribution of the virus, and the virus being in a controlled status with the country or countries heading toward eventual DMRVV-free status.

DMRVV high-risk countries means countries assessed by CDC as high risk for DMRVV transmission based on factors such as the presence and geographic distribution of the virus or low quality of or low confidence in rabies surveillance systems or dog vaccination programs.

DMRVV-restricted countries means countries for which the export of dogs into the United States has been prohibited or otherwise restricted based on the countries' export of dogs infected with DMRVV to any other countries within a period determined by CDC or based on evidence of lacking adequate controls, as determined by CDC, to monitor and prevent the export of dogs to the United States with falsified or fraudulent vaccine credentials, invalid rabies vaccination forms, or other fraudulent, inaccurate, or invalid importation documents.

Importer of dogs or cats means any person importing or attempting to import a dog or cat into the United States, including the animal's legal owner or a person acting on behalf of the

importer, such as a broker licensed with CBP. Individuals compensated or hired to transport animals on behalf of the importer must have a valid USDA license or registration. CDC believes that requiring that individuals who are compensated or hired to transport animals have a valid USDA license or registration pursuant to the Animal Welfare Act would help deter fraudulent conduct.

HHS/CDC is also providing a new definition for what constitutes proof of rabies vaccination. These definitions are needed to provide clarity regarding HHS/CDC's proposed admission requirements.

CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States Form means the OMB-approved form¹⁰¹ that must be: (1) completed by an Authorized Veterinarian in the exporting country, which may include an Official Government Veterinarian in the exporting country; and (2) reviewed and certified by an Official Government Veterinarian in the exporting country attesting that the information listed is true and correct.

Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States Form means the OMB-approved form¹⁰² that must be completed by a USDA-Accredited Veterinarian and certified by a USDA Official Veterinarian prior to exporting a dog from the United States in order to demonstrate compliance with admissibility requirements upon returning to the United States.

SAFE TraQ means the System for Animal Facilities Electronic Tracking of Quarantine or other system as approved by the Director for tracking the quarantine of animals approved for admission into the United States.

Serologic Testing, when applied to an imported animal, means an antibody titration test performed by a CDC-approved rabies laboratory using a CDC-approved technique. The serology

¹⁰¹ OMB approval no. 0920-1383 (exp. 1/31/26).

¹⁰² OMB approval no. 0579-0020,0036,0048,0101,0156,0278,0432.

sample must be drawn and submitted in accordance with CDC technical instructions. The current list of CDC-approved laboratories is available online.

USDA-Accredited Veterinarian is defined in 9 CFR 160.1 and is an Accredited Veterinarian who has completed formal training from the National Veterinary Accreditation Program in the State in which they are licensed to practice as a veterinarian.

USDA Official Veterinarian is a USDA/APHIS veterinarian who is assigned by the USDA Administrator to supervise and perform official work of APHIS in a State or group of states.

(b) Authorized U.S. airports for dogs and cats.

Dogs from DMRVV-free or DMRVV low-risk countries that have not been in any DMRVV high-risk country within the last six months and all cats may continue to enter through any U.S. port. CDC does not currently have any restrictions on the U.S. ports for dogs arriving in the United States from DMRVV high-risk countries. Through this NPRM, HHS/CDC proposes that if a U.S.-vaccinated dog has been in a DMRVV high-risk country in the previous six months, the dog must arrive at an airport with a CDC quarantine station. The importer would also be required to have a USDA-Accredited Veterinarian complete the *Certification of U.S.-Issued Rabies Vaccination For Live Dog Re-entry into the United States* Form and present this form to the airline prior to boarding. All foreign-vaccinated dogs that have been in a DMRVV high-risk country in the previous six months would be required to enter the United States at a U.S. airport with a CDC quarantine station and a CDC-registered Animal Care Facility. The importer would also be required to have an Authorized Veterinarian complete the *CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States* Form and present this form to the airline prior to boarding.

This requirement that dogs from DMRVV high-risk countries arrive at specified airports is being proposed to ensure dogs can be evaluated by CDC quarantine station staff or a USDA-

Accredited Veterinarian upon arrival to confirm they have all required documentation for admission and do not appear ill. Visual examinations of animals may be conducted by CDC quarantine station staff to look for overt signs of illness (i.e., vomiting, diarrhea, bleeding, seizures, or ocular or nasal discharge). Animals showing signs of illness will not be released for entry until a USDA-Accredited Veterinarian completes a physical exam and administers a USDA-licensed rabies vaccine (if applicable). As of June 1, 2023, five U.S. airports have CDC-registered Animal Care Facilities. The CDC-registered Animal Care Facilities will help to ensure animals that arrive ill, or must be detained, will be held in a facility that meets CDC requirements, USDA Animal Welfare Act Standards,¹⁰³ and maintains an active CBP FIRMS code. This requirement would further help ensure that facilities have staff who are properly trained to provide food, water, shelter, and veterinary care to animals if needed. CDC will continue to register live-animal care facilities at the remaining 13 U.S. airports with CDC quarantine stations to protect the health and safety of airline and warehouse staff, as well as the health and safety of animals arriving in the United States at these ports.

(c) Authorized U.S. land ports for dogs and cats.

HHS/CDC is not proposing any changes to the authorized U.S. land ports for dogs arriving to the United States from DMRVV low-risk or DMRVV-free countries that have not been in a DMRVV high-risk country within the last six months. There are also no proposed changes for cats; cats may continue to enter through any U.S. port, including land ports. CDC is proposing to prohibit entry into the United States through any U.S. land port for dogs that have been in a DMRVV high-risk country within the last six months. There are no CDC-registered Animal Care Facilities along the U.S.-Mexico and U.S.-Canada borders that can safely house or quarantine dogs arriving from DMRVV high-risk countries. Additionally, local and State animal and public health authorities do not have capacity on a routine basis to house and quarantine

¹⁰³ 7 U.S.C. 2148.

dogs arriving from DMRVV high-risk countries without additional burdens being placed on local public health resources.

(d) Authorized U.S. seaports for dogs and cats.

HHS/CDC is not proposing any changes to the authorized U.S. seaports for dogs arriving to the United States from DMRVV low-risk or DMRVV-free countries that have not been in any DMRVV high-risk country within the last six months. There are also no proposed changes for cats; cats may continue to enter through any U.S. port, including seaports. HHS/CDC is proposing to prohibit entry into the United States through any U.S. seaport for dogs that have been in a DMRVV high-risk country within the last six months. There are no CDC-registered Animal Care Facilities at U.S. seaports that can safely house or quarantine dogs arriving from DMRVV high-risk countries. Additionally, local and State animal and public health authorities do not have capacity on a routine basis to house and quarantine dogs arriving from DMRVV high-risk countries without additional burdens being placed on local public health resources.

However, HHS/CDC is proposing an exception for dogs meeting the definition of a “service animal” under 14 CFR 382.3 that have been in a DMRVV high-risk country within the last six months. HHS/CDC would permit entry if the dog is accompanied by an “individual with a disability” as defined under 14 CFR 382.3 and the dog does work or performs tasks that are directly related to the individual's disability. CDC believes this exception would apply to a small number of individuals who require that their service dog accompany them on cruise ships with U.S. destination ports. The dog must be otherwise admissible under this section and would be allowed entry if:

1. The dog was vaccinated against rabies in the United States and is accompanied by a valid *Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States* Form; or

2. The dog was vaccinated against rabies in a foreign country and is accompanied by both a valid foreign-issued *CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States* Form and a valid serologic titer from a CDC-approved laboratory.

(e) Limitation on U.S. ports for dogs and cats.

HHS/CDC is proposing to explicitly authorize the Director to limit the times, U.S. ports, and/or conditions under which dogs or cats may arrive at and be admitted to the United States based on an importer's or carrier's failure to comply with the provisions of this section or as needed to protect the public's health. If the Director determines such a limitation is required, the Director will notify importers or carriers in writing of the specific times, U.S. ports, and/or conditions under which dogs and cats may be permitted to arrive at and be admitted to the United States.

(f) Age requirement for all dogs.

Through this NPRM, HHS/CDC proposes that all dogs arriving into the United States (regardless of whether from DMRVV-free, DMRVV low-risk, or DMRVV high-risk countries) be, at minimum, six months of age. HHS/CDC currently requires dogs to be at least four months of age to enter the United States if arriving from a DMRVV high-risk country because this is the age at which a dog can be considered adequately vaccinated for rabies. Verification of a dog's age is made via dental examination, with dogs six months of age or older being easily identified by the presence of adult incisors and canine teeth. HHS/CDC is proposing to require imported dogs be at least six months of age, which would allow veterinarians to more easily estimate the ages of young dogs to ensure adequate DMRVV vaccination.

The proposed requirement that all dogs arriving into the United States be at least six months of age will align with USDA/APHIS Animal Care requirements for the importation of

dogs that are being imported for rescue or resale and will help ensure pet dogs can be safely transported without risk to their health and welfare. HHS/CDC is proposing as an exception to allow an importer to import a maximum of three personal pet dogs under six months of age in a calendar year if arriving via a U.S. land port from Canada or Mexico if the dog has not been in a DMRVV high-risk country in the previous six months.

Based on communication with Federal partner agencies and data in CDC's quarantine activity reporting system, persons importing three or more dogs in a calendar year are less likely to be doing so in connection with their personal pet ownership and more likely to be associated with commercial importations of animals, including importers attempting to circumvent HHS/CDC entry requirements by transporting dogs from DMRVV high-risk countries through Canada and Mexico for resale or adoption in the United States. Therefore, HHS/CDC proposes this age requirement to protect public health, as well as the health and safety of young puppies being purchased and sold internationally.

(g) Microchip requirements for all dogs.

HHS/CDC does not currently require a microchip for importation of dogs into the United States. Requiring a microchip for all dogs would help ensure that veterinary paperwork and animal identification can be verified. It will also align with the admission requirements of other DMRVV-free countries and bring the United States into international alignment with the World Organisation for Animal Health (WOAH) standards that all dogs have permanent identification or marking for international movement.¹⁰⁴ HHS/CDC proposes to require that all dogs have an Individual Standards Organization (ISO)-compliant microchip prior to arrival in the United States or prior to traveling out of the United States and returning.

¹⁰⁴ World Organisation for Animal Health. Terrestrial Code Online Access - WOAH - World Organisation for Animal Health: https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmlfile=chapitre_certif_rabies.htm.

(h) *CDC Import Submission Form* for all dogs.

CDC and Federal partners have documented numerous instances of importers moving dogs from DMRVV high-risk countries through DMRVV low-risk country to circumvent U.S. dog entry requirements.^{105, 106} HHS/CDC proposes requiring that importers submit a *CDC Import Submission Form* via a CDC-approved system for each imported dog to help mitigate the risk of importers presenting dogs from DMRVV high-risk countries at U.S. ports that have traveled through DMRVV low-risk countries for short periods of time (less than six months) and do not meet CDC entry requirements. The *CDC Import Submission Form* must be submitted to CDC prior to a dog's departure from the foreign country.

(i) Inspection requirements for admission of dogs and cats.

HHS/CDC currently requires that all dogs and cats arriving in the United States be inspected to ensure they appear healthy. While the requirement for inspection of dogs and cats is not new, HHS/CDC proposes clarifying that dogs and cats may be denied admission if an importer refuses to consent to the required screening. HHS/CDC believes that this additional clarification is needed because of numerous documented instances of confusion among importers and some carriers regarding CDC's ability to mandate a public health evaluation of a dog or cat prior to admission. Additionally, CDC may coordinate with other federal and state partners to engage in routine disease surveillance of animals arriving in the United States.

(j) Examination by a USDA-Accredited Veterinarian and confinement of exposed dogs and cats or those that appear unhealthy.

¹⁰⁵ The importer of the rabid dog into the United States in 2019 first flew into Canada before crossing a land border into the United States. See Raybern, C et al. Rabies in a dog imported from Egypt-Kansas, 2019. *MMWR Morb Mort Wkly Rep* 2020; 69 (38): 1374-1377.

¹⁰⁶ Centers for Disease Control and Prevention. Quarantine Activity Reporting System (version 4.9.8.2.2A). Dog importation data, 2018-2020. Accessed: February 15, 2021.

HHS/CDC currently requires examination by a veterinarian and confinement if, upon examination, a dog or cat appears unhealthy upon arrival, and such measures are needed to protect the public's health. While the requirement for examination and confinement are not new, this proposed provision is primarily intended to require airlines to assume responsibility for housing and caring for dogs and cats that arrive sick in the event the importer abandons the shipment. CDC has documented numerous instances of sick animals not receiving care in a timely manner and animals denied admission being left by airlines in unacceptable housing conditions.

HHS/CDC proposes, in the event a dog or cat arrives ill, is denied admission, or is exposed to a sick animal in transit,^{107,108} that the airline arrange for confinement in a CDC-approved veterinary clinic and that the importer bears the expenses of such confinement, examination, testing, and treatment. If an importer fails to pay for such expenses, then the animal may be considered abandoned, and the airline will be required to assume financial responsibility. This provision is needed to help ensure airlines assume responsibility for sick or exposed dogs and cats and that such animals do not remain in unsafe conditions for prolonged periods of time (e.g., longer than six hours). The proposed rule further clarifies an airline's responsibilities in the event an importer abandons a dog or cat. This provision may also be applied to other carriers transporting dogs and cats in the rare circumstances where it is necessary for public health reasons to require that the carrier arrange for examination and confinement.

(k) Veterinary examination and revaccination against rabies at a CDC-registered Animal Care Facility for foreign-vaccinated dogs.

¹⁰⁷ National Association of State Public Health Veterinarians. Compendium of animal rabies prevention and control, 2016. *JAVMA* 2016; 248 (5):505-517.

¹⁰⁸ Manning SE, Rupprecht CE, Fishbein D, et al. Human rabies prevention—United States, 2008: recommendations of the Advisory Committee on Immunization Practices. *MMWR Recomm Rep* 2008;57(RR-3):1–28.

HHS/CDC proposes to require all dogs arriving from DMRVV high-risk countries without a valid *Certification of U.S.-Issued Rabies Vaccination for Live Dog Re-entry into the United States* Form to have a valid *CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States* Form and undergo veterinary examination and revaccination against rabies at a CDC-registered Animal Care Facility upon arrival.

The importer would be responsible for making a reservation and all arrangements relating to the examination, revaccination, and quarantine (if quarantine is required) of dogs with a CDC-registered Animal Care Facility prior to the dogs' arrival in the United States. Airlines must deny boarding to dogs if the importer fails to present a receipt of the completed *CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States* Form. The costs of examination, vaccination, and quarantine (if required) would be borne by the importer and not the United States Government. Animals that are abandoned before meeting requirements outlined below become the legal responsibility of the airline.

HHS/CDC proposes that the dogs remain in the custody of a CDC-registered Animal Care Facility until all of the following requirements are met:

- (i) Veterinary health examination by a USDA-Accredited Veterinarian for signs of disease. Suspected or confirmed zoonotic or foreign animal diseases would be required to be reported to CDC, USDA, the State or County Public Health Veterinarian, and the State Veterinarian prior to release of the animals.
- (ii) Vaccination against rabies with a USDA-licensed rabies vaccine and administered by a USDA-Accredited Veterinarian.
- (iii) Confirmation of microchip number.
- (iv) Confirmation of age through dental examination by a USDA-Accredited Veterinarian.
- (v) Verification of adequate rabies serologic test from a CDC-approved laboratory. To be considered valid, serologic tests must be drawn prior to arrival within an established timeframe

and display results within parameters as specified in CDC technical instructions.¹⁰⁹ Currently, this means that serologic tests must be drawn 45 to 365 days before arrival and have a result greater than or equal to 0.5 IU/mL. Dogs that arrive without an adequate rabies serologic test results from a CDC-approved laboratory would be housed at the CDC-registered Animal Care Facility for a 28-day quarantine following administration of the U.S. rabies vaccine or until an adequate rabies serologic test from a CDC-approved laboratory is confirmed.

(l) Registration or renewal of CDC-registered Animal Care Facilities.

Through this NPRM, HHS/CDC proposes to establish a registration mechanism for CDC-registered Animal Care Facilities used in the importation of foreign-vaccinated dogs arriving in the United States from DMRVV high-risk countries. Before housing any imported live dog in the United States, an animal care facility would be required to register with and receive written approval from CDC, USDA, and CBP to submit their facility application. The applicant would need to provide written standard operating procedures outlining how CDC's regulatory requirements will be met and the health and safety of animals and staff will be ensured. A copy of all Federal, State, or local registrations, licenses, or permits would also be required to be submitted to CDC. Additionally, CDC would require the facility to have a USDA intermediate handlers license and a FIRMS code issued by CBP. The facility would be subject to inspection by CDC at least annually and required to renew their registration every two years. Animal health records, facilities, vehicles, or equipment to be used in receiving, examining, and processing imported animals would also be subject to inspection.

(m) Record-keeping requirements at CDC-registered Animal Care Facilities.

¹⁰⁹ CDC Technical Instructions will be posted to CDC's website (www.cdc.gov/dogtravel) upon publication of the final rule.

HHS/CDC proposes to require that any CDC-registered Animal Care Facilities retain records regarding each imported animal for three years after the distribution or transfer of the animal. Each record must include:

- (i) The bill of lading for each shipment;
- (ii) The name, address, phone number, and email address of the importer and owner (if different from the importer);
- (iii) The number of animals in each shipment;
- (iv) The identity of each animal in each shipment, including name, microchip number, date of birth, sex, breed, and coloring;
- (v) The airline, flight number, date of arrival, and port of each shipment; and
- (vi) Veterinary medical records for each animal, including:
 - (a) *CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States* Form and rabies serology obtained before arrival in the United States (if applicable);
 - (b) The USDA-licensed rabies vaccine administered upon arrival;
 - (c) Veterinary exam records upon arrival and while in quarantine;
 - (d) Rabies serology performed while in quarantine in the United States (if applicable);
 - and
 - (e) All diagnostic test, histopathology and necropsy results performed during quarantine (if applicable).

The facility would be required to maintain these records electronically and allow CDC to inspect the records.

- (n) Worker protection plan and personal protective equipment (PPE).

HHS/CDC proposes to require that a CDC-registered Animal Care Facility establish and maintain a worker protection plan with standards comparable to those in CDC's National

Institute for Occupational Safety and Health (NIOSH) Veterinary Safety and Health guidelines¹¹⁰ and the National Association of Public Health Veterinarians (NASPHV) Compendium of Veterinary Standard Precautions for Zoonotic Disease Prevention in Veterinary Personnel.¹¹¹ Such a worker protection plan must include rabies pre-exposure prophylaxis for workers handling imported animals in quarantine, post-exposure procedures that provide potentially exposed workers with direct and rapid access to a medical consultant, and procedures for documenting the frequency of worker training, including for those working in the quarantine area. As part of the worker protection plan, a facility would also need to establish, implement, and maintain hazard evaluation and worker communication procedures that include descriptions of the known zoonotic disease and injury hazards associated with handling animals, the need for PPE when handling animals and training in the proper use of PPE, and procedures for disinfection of garments, supplies, equipment, and waste.

(o) CDC-registered Animal Care Facility standard operating procedures, requirements, and equipment standards for crating, caging, and transporting live animals.

HHS/CDC proposes to outline equipment standards for crating, caging, and transporting live animals for CDC-registered Animal Care Facilities. The standards must be in accordance with USDA Animal Welfare regulation standards¹¹² (9 CFR parts 1, 2, and 3) and International Air Transport Association standards.¹¹³ Violations of the USDA Animal Welfare Act may result in immediate revocation of an animal care facility's status as a CDC-registered Animal Care Facility.

(p) Health reporting requirements for animals at CDC-registered Animal Care Facilities.

¹¹⁰ <https://www.cdc.gov/niosh/topics/veterinary/biological.html>.

¹¹¹ <http://www.nasphv.org/Documents/VeterinaryStandardPrecautions.pdf>.

¹¹² U.S. Department of Agriculture. Animal Welfare Act. https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_awa. Accessed June 7, 2023.

¹¹³ International Air Transport Association. Live Animals. <https://www.iata.org/en/programs/cargo/live-animals>. Accessed June 7, 2023.

HHS/CDC proposes to establish health reporting requirements for all dogs being evaluated at a CDC-registered Animal Care Facility. A facility would need to provide the following services for each dog from a DMRVV high-risk country with a foreign-issued rabies vaccine upon arrival and ensure each animal meets CDC, USDA, and state and local entry requirements prior to release from the facility:

- (i) Veterinary examination by a USDA-Accredited Veterinarian within one business day of arrival;
- (ii) Verification of microchip and confirmation that the microchip number matches the animal's health records;
- (iii) Verification of animal's age via a dental examination;
- (iv) Vaccination against rabies using a USDA-licensed vaccine; and
- (v) Verification of an adequate serologic test from a CDC-approved laboratory OR 28-day quarantine after administration of the USDA-licensed rabies vaccine.

HHS/CDC further proposes that the facility notify CDC within 24 hours of the occurrence of any morbidity or mortality of animals in the facility. Any animal that dies at a CDC-registered Animal Care Facility would be required to undergo a necropsy and diagnostic testing to determine the cause of death. An animal that arrives ill or becomes ill while at the CDC-registered Animal Care Facility would need to be examined by a USDA-Accredited Veterinarian immediately and undergo diagnostic testing to determine the cause of illness prior to release from the facility. Suspected or confirmed zoonotic diseases would need to be reported to CDC and the State or County Public Health Veterinarian within 24 hours of identification. Suspected or confirmed foreign animal diseases or infectious animal diseases would be reported to USDA and the State or County Veterinarian within 24 hours of identification.¹¹⁴

¹¹⁴ Zoonotic disease are diseases that can spread from animals to people; infectious animal diseases spread only between animals; foreign animal diseases are not present in the United States and may or may not be zoonotic.

(q) Quarantine requirements for CDC-registered Animal Care Facilities.

HHS/CDC proposes to establish requirements for the quarantine area at CDC-registered Animal Care Facilities to ensure animals are safely housed and do not present a public health risk to humans or other animals. The proposed requirements include building security to prevent unintended public exposure to quarantined animals, cleaning and disinfection standards, and diagnostic testing or necropsy for ill or deceased animals.

(r) Revocation and reinstatement of a CDC-registered Animal Care Facility's registration.

HHS/CDC proposes procedures to revoke a CDC-registered Animal Care Facility's registration if the Director determines that it has failed to comply with any applicable provisions of this section. CDC would send the facility a notice of revocation stating the grounds upon which the proposed revocation is based. If the facility contested the revocation, the facility would be required to file a written response to the notice within five business days after receiving the notice. All the grounds listed in the proposed revocation would be deemed admitted if the facility failed to respond.

If a facility's response is timely, the Director will review the registration, the notice of revocation, and the response. The Director would then decide whether to revoke the facility's registration based on the written record and communicate this decision in writing to the facility. The Director could reinstate a revoked registration after inspecting the facility, examining its records, conferring with the facility, and receiving information and assurance from the facility of compliance with the requirements of this section.

(s) Requirement for the *CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States* Form to import a foreign-vaccinated dog from DMRVV high-risk countries.

HHS/CDC currently requires in 42 CFR 71.51(c) that importers of dogs arriving from DMRVV high-risk countries provide a valid RVC, as defined in 42 CFR 71.51(a), upon arrival; this includes proof of vaccination but importers are not required to use a standardized form. Without a standardized form, there is tremendous variation among countries in documenting proof of vaccination. This lack of standardization creates confusion for port staff who are responsible for reviewing the rabies proof of vaccination.

Through this NPRM, HHS/CDC proposes to require a new, standardized rabies vaccination form for all foreign-vaccinated dogs arriving from DMRVV high-risk countries. This rabies vaccination form will be standardized and help importers and Federal agencies ensure dogs being imported from DMRVV high-risk countries are imported with all the required information on one form. This requirement will reduce confusion and ensure Official Government Veterinarians in the exporting country have reviewed the veterinary records and examined dogs prior to travel. HHS/CDC proposes that this form replace the current valid RVC requirement, which was not aligned with internationally accepted standards for the international movement of animals. This form will also permit CDC and other U.S. Government agencies to confirm the accuracy of documentation with exporting country officials if discrepancies in the forms are noted.

All foreign-vaccinated dogs from DMRVV high-risk countries will be required to be examined by a USDA-Accredited Veterinarian and revaccinated with a USDA-licensed vaccine at a CDC-registered Animal Care Facility upon arrival to align with State rabies vaccination requirements and recommendations from the NASPHV.¹¹⁵ Dogs arriving without a *Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States* form will be required to present the *CDC Import Certification of Rabies Vaccination and Microchip Required*

¹¹⁵ National Association of State Public Health Veterinarians. Compendium of Animal Rabies Prevention and Control, 2016. JAVMA 2016; 248 (5): 505-517.

for Live Dog Importations into the United States form to the CDC-registered Animal Care Facility along with a valid serologic test from a CDC-approved laboratory (if applicable).

To be considered valid, serologic tests must be drawn prior to arrival within a timeframe and display results within parameters as specified in CDC technical instructions. Currently, to be considered valid, serologic tests must be drawn within a timeframe of 45 to 365 days before arrival and have a result greater than or equal to 0.5 IU/ml. Dogs that arrive without an adequate rabies serologic test from a CDC-approved laboratory will be subject to a mandatory 28-day quarantine after revaccination at a CDC-registered Animal Care Facility at the importer's expense. HHS/CDC is requesting public comments on all aspects of this proposal as it relates to persons traveling abroad with their dogs.

(t) Requirement for *Certification of U.S.-Issued Rabies Vaccination for Live Dog Re-entry into the United States* Form for importers seeking to import U.S.-vaccinated dogs from DMRVV high-risk countries.

HHS/CDC proposes to require that U.S.-vaccinated dogs re-entering the United States from DMRVV high-risk countries arrive at a U.S. airport with a CDC quarantine station and be accompanied by a *Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States* Form. The form must be completed by a USDA-Accredited Veterinarian and signed by a USDA Official Veterinarian prior to the animal departing the United States. Importers returning to the United States from a DMRVV high-risk country with this form may present their dog for admission without a rabies serologic test from a CDC-approved laboratory, without the dog undergoing veterinary examination (unless ill, injured, or exposed), and without revaccination against rabies at a CDC-registered Animal Care Facility. People who leave the United States with their dogs without first obtaining this form will be required to have their dogs re-enter the United States as if they are foreign-vaccinated dogs and be required to meet all the

requirements as outlined in section (s) for the dogs to be eligible for re-entry from a DMRVV high-risk country. HHS/CDC solicits feedback on this proposed process.

(u) Requirement for proof that a dog has only been in a DMRVV low-risk or DMRVV-free country.

HHS/CDC proposes to require that dogs being imported from DMRVV low-risk or DMRVV-free countries be accompanied by appropriate written documentation demonstrating that they have not been in any DMRVV high-risk country during the past six months. An importer would need to provide written documentation, such as veterinary medical records, upon request confirming that the dog is at least six months of age, is microchipped, and has been only in a DMRVV low-risk or DMRVV-free country for the six months prior to importation into the United States. There are no proposed changes for cat rabies vaccination importation requirements. CDC recommends importers comply with State or Territorial requirements for rabies vaccination in cats. The *CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States* form would not be required for importers able to meet the requirements of this paragraph. HHS/CDC is requesting public comment on whether a standardized form should be required for dogs arriving from DMRVV-free and DMRVV low-risk countries in order to avoid potential fraud. HHS/CDC is requesting public comment on all aspects of this proposal as it relates to cats and dogs.

(v) Denial of admission of dogs and cats.

This proposed section outlines the circumstances under which CDC can deny admission to a dog or cat being presented for admission into the United States. CDC shall notify CBP in writing to enforce this action. This includes:

- Any dog arriving from a DMRVV low-risk or DMRVV-free country without written documentation that the dog has resided in a DMRVV low-risk or rabies-free country for the six months prior to the attempted entry, or if the Director reasonably suspects fraud.
- Any dog that is not accompanied by a receipt confirming that a *CDC Import Submission Form* has been submitted to CDC through a CDC-approved system.
- Any dog arriving at a U.S. airport for which a bill of lading has not been created by the airline prior to arrival.
- Any dog arriving at a U.S. land port that has been in a DMRVV high-risk country within the last six months prior to the attempted entry.
- Any dog arriving at a U.S. seaport that has been in a DMRVV high-risk country within the last six months prior to the attempted entry, except for a dog qualifying as a service animal that is otherwise admissible under this section.
- Any dog imported by an importer who refuses to comply with the requirement (if applicable) for the dog to undergo disease surveillance screening, veterinary examination, revaccination, provide proof of sufficient rabies serologic tests, or quarantine at a CDC-registered Animal Care Facility upon arrival.
- Any dog that has been in a DMRVV high-risk country in the previous six months and arrives without a valid *Certification of U.S.-Issued Rabies Vaccination for Live Dog Re-entry into the United States* Form or a valid *CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States* Form.
- Any dog that has been in a DMRVV high-risk country in the previous six months and does not arrive via air at a U.S. airport with a CDC quarantine station or via air at a U.S. airport with a CDC-registered Animal Care Facility (if applicable).
- Any dog imported from a DMRVV high-risk country that arrives without a reservation at a CDC-registered Animal Care Facility (if applicable).

- Any dog from a DMRVV-restricted country that arrives without a valid *CDC Dog Import Permit*.
- Any dog imported from a DMRVV high-risk country if the Director reasonably suspects fraud in any documentation required for admission or if such documentation is otherwise untruthful, inaccurate, or incomplete.
- Any dog or cat, regardless of country of departure, that poses a public health risk, including dogs or cats that appear unhealthy upon arrival or demonstrate signs or symptoms of communicable disease.
- Any dog under six months of age that is arriving at a U.S. airport or seaport, or any dog under six months of age that is arriving at a U.S. land port if the importer has imported three or more individual dogs under six months of age in the same calendar year (January-December).

HHS/CDC solicits public comment regarding this proposed paragraph, including whether the grounds for the proposed denial of admission are sufficient to protect the public's health.

(w) Disposal or disposition of dogs and cats denied admission or abandoned prior to admission that were transported to the United States.

Through this NPRM, HHS/CDC proposes an operational framework primarily applicable to airlines regarding how dogs denied admission would be handled by carriers and importers. HHS/CDC clarifies that airlines must provide housing for animals awaiting return to their country of departure at a CDC-registered Animal Care Facility or a CDC-approved animal facility if a CDC-registered Animal Care Facility is not available. Airlines are required to return animals denied admission to the country of departure within 72 hours of arrival, regardless of carrier or route. This is to ensure airlines do not leave animals in warehouses unattended for prolonged periods of time. As proposed, airlines would be able to request extensions for an animal's return in the event the animal is not medically fit for travel. This proposed operational

framework provides that importers are responsible for all associated costs relating to the housing, care, and treatment of a dog or cat denied admission pending return to its country of departure. However, if an importer fails to pay any costs or fails to comply with any requirements, the animal will be considered abandoned, and the relevant carrier would be required to assume responsibility.

In instances where a dog or cat is fatally ill or injured, the importer or airline may choose a humane euthanasia option in accordance with the standards of the American Veterinary Medical Association¹¹⁶ performed by a licensed veterinarian. The importer or airline must notify CDC and CBP in writing of this decision. This decision does not relieve the importer or airline of the obligation to obtain and report results of necropsy or diagnostic testing required by CDC.

In the case of dogs and cats denied admission to the United States upon arrival at a U.S. seaport, the vessel's master or operator would be required to reembark the animal immediately and return it to its country of departure on the next voyage. In the case of dogs and cats denied admission to the United States upon arrival at a U.S. land port, the importer or carrier would be required to immediately return it to its country of departure.

CDC does not expect the above operational framework relating to housing, care, and treatment of a dog or cat denied admission to be applied on a routine basis to carriers or importers arriving with dogs or cats at U.S. land or seaports because the circumstances leading to a delay in returning a dog or cat to its country of departure are not typically present at these U.S. ports. However, CDC acknowledges that there may be rare and unforeseen circumstances where it may be necessary to apply such procedures. Accordingly, CDC has added language authorizing it to apply these provisions in circumstances where a dog or cat is denied entry at a U.S. land or seaport and cannot be immediately returned to its country of departure (e.g., because it is unfit to travel). HHS/CDC specifically solicits public comment regarding the possible

¹¹⁶ <https://www.avma.org/resources-tools/avma-policies/avma-guidelines-euthanasia-animals>.

application of these measures to dogs and cat arriving in the United States at U.S. land or seaports.

(x) Appeals of CDC denials to admit a dog or a cat upon arrival into the United States.

This section proposes an appeal process for importers of dogs and cats in the event their animals are denied admission to the United States upon arrival.

If CDC denies admission to a dog or cat under this section, the importer may appeal that denial to the Director. The importer must submit the appeal in writing to the Director that states the reasons for the appeal and demonstrates that there is a genuine and substantial issue of fact in dispute. The importer must submit the appeal within one business day of the denial. Submitting an appeal will not delay the return of the animal to the country of departure. CDC will issue a written response, which shall constitute final agency action.

Because denial of admission to dogs and cats under these limited circumstances is likely to occur at a port, HHS/CDC proposes that any appeal be submitted within one business day so as not to unnecessarily prolong the appeal process and allow for expedited decision-making regarding whether an animal should be returned to its country of departure. Pending a determination regarding the appeal the animal will remain the legal responsibility of the carrier. HHS/CDC solicits public comment regarding this proposal.

(y) Record of death of dogs and cats while en route to the United States and disposition of dead animals.

The requirement that carriers maintain a record of sickness or death for any animals that die during transit is longstanding. Through this NPRM, HHS/CDC proposes to require necropsy and diagnostic testing for any dog or cat that dies *en route* to the United States or at a U.S. port prior to admission to determine the cause of death. Consistent with current requirements, carriers would be required to report deaths to the CDC quarantine station of jurisdiction. HHS/CDC

proposes these amendments to ensure it can detect, provide referrals to appropriate agencies, and respond to potential zoonotic disease importation risks in a timely manner. Importers would be responsible for the costs unless they abandon the animal, in which case the airline or master or operator of a vessel would assume responsibility for the costs.

(z) Abandoned shipments of dogs and cats.

Through this NPRM, HHS/CDC proposes an operational framework primarily applicable to airlines for when a dog or cat would be considered abandoned prior to admission and thus require the carrier to assume responsibility for the shipment. CDC has documented several instances in which importers have chosen to abandon dogs. Federal and State public health agencies have incurred financial costs because of importers abandoning dogs and the subsequent refusal by airlines to provide safe housing and return for dogs. HHS/CDC proposes that an animal shipment be deemed abandoned under the following circumstances:

- When explicitly stated by the importer verbally or in writing to the carrier, CDC, or CBP;
or
- If the importer fails to cooperate with or respond to the carrier's attempts to comply with the regulations listed in 42 CFR 71.51 within 24 hours; or
- If the importer refuses payment within 24 hours for CDC-mandated examinations, testing, holding, or treatment needed to ensure the safe importation of animals into the United States.

The provisions of this paragraph may also be applied to other carriers transporting such dogs and cats in the rare circumstances where the dog or cat is abandoned by the importer at a U.S. land port or seaport and other options are not available.

(aa) Sanitation of cages and containers of dogs and cats.

The requirement that animal cages and containers be kept in a sanitary condition is long-standing. This language appears as a separate paragraph in the proposed regulation, but HHS/CDC is not proposing any changes to the existing language, which requires that animals be transported in clean crates or cages. CDC is republishing this section to provide context and for the convenience of the reader.

(bb) Requirements for in-transit shipments of dogs and cats.

HHS/CDC proposes to clarify the definition of an in-transit shipment and outlines the requirements for dogs and cats that transit the United States as part of an in-transit shipment. CDC's definition would align with that of the USDA, and HHS/CDC clarifies that dogs and cats cannot be considered in transit if they are transported as hand-carried baggage or checked baggage. In-transit shipments may only be transported as cargo.

(cc) Bill of lading and other airline requirements for dogs

To help mitigate the risk of importers presenting dogs from DMRVV high-risk countries at U.S. airports that have traveled through DMRVV low-risk countries for short periods of time (less than six months) and do not meet CDC entry requirements, this NPRM proposes to require that airlines create a bill of lading accounting for all live dog imports through a U.S. airport, regardless of whether the dogs are transported as cargo, checked baggage, or hand-carried baggage, or otherwise accompany a traveler arriving in the United States on their person. Requiring airlines to create a bill of lading specifically for all live dog imports arriving at a U.S. airport will also help ensure airlines are accountable for the safety of the dog upon arrival in the United States. Dogs that do not have bills of lading by an airline are more likely to be left by the

airline in unsafe conditions, and airlines often refuse to take responsibility for the safety and entry requirements for dogs flown as checked-baggage or hand-carried baggage.¹¹⁷

CDC also proposes to require that airlines confirm that all importers have a receipt of a completed *CDC Import Submission Form* prior to boarding. For U.S.-vaccinated dogs, CDC proposes that airlines confirm that importers have a valid *Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States Form*. For foreign-vaccinated dogs, CDC proposes that airlines confirm that importers have a reservation at a CDC-registered Animal Care Facility. For dogs from DMRVV-free or low-risk countries, CDC proposes that airlines confirm that the importer has documentation showing that the dog is over six months of age, has a microchip, and has not been in a DMRVV high-risk country in the previous six months.

CDC is also proposing that a representative of an airline transporting live dogs into the United States be on-site at the U.S. airport and available to coordinate the entry/clearance of the dogs with federal government officials until all live dogs transported on an arriving flight into the United States have either been cleared for admission or arrangements have been made to transport the dogs to a CDC-registered Animal Care Facility or other facility (e.g., veterinary clinic or kennel) approved by CDC pending admissibility determination.

HHS/CDC is seeking public comment on whether airline staff should be required to present dogs for entry and be available until all dogs have been cleared for entry or arrangements have been made to transport the dogs to a CDC-registered Animal Care Facility or other facility (e.g., veterinary clinic or kennel) approved by CDC pending an admissibility determination. HHS/CDC is also seeking public comment on how airlines can present dogs for inspection in the cargo area, except dogs meeting the definition of a “service animal” under 14 CFR 382.3.

¹¹⁷ Centers for Disease Control and Prevention. Quarantine Activity Reporting System (version 4.9.8.8.2.2A). Dog importation data, 2018-2020. Accessed: February 15, 2021.

(dd) Order prohibiting carriers from transporting dogs and cats.

HHS/CDC proposes procedures for the Director to issue an order revoking a carrier's permission to transport live dogs and cats into the United States if a carrier has endangered the public health of the United States by acting or failing to act to prevent the introduction of DMRVV, as would occur by failing to comply with the provisions of this section. HHS/CDC believes that the circumstances giving rise to such an order would be exceedingly rare, such that HHS/CDC would issue an order only after repeated attempts to consult with and obtain voluntary compliance and remedial action from the carrier have failed. The Director would rescind the order after working with the carrier to obtain remedial action, such as: inspecting the carrier's facilities; examining its records; conferring with the carrier's owners or operators, contractors, or staff; or after receiving information and written assurances from the carrier owner or operator that it has taken remedial steps to ensure future compliance with HHS/CDC dog and cat importation requirements. Such an order would be subject to an administrative appeal. The appeal must be in writing, addressed to the Director, state the reasons for the appeal, and demonstrate that there is a genuine and substantial issue of fact in dispute. As soon as practicable after completing the appeal review, the Director will issue a decision in writing that would constitute final agency action. The Director will serve the carrier owners or operators with a copy of the written decision.

(ee) Prohibition on imports of dogs from DMRVV-restricted countries.

Through this NPRM, HHS/CDC proposes to prohibit or otherwise restrict the import of dogs into the United States from certain countries that have repeatedly exported rabid dogs to any other country or that lack adequate controls to monitor and prevent the export of dogs to the United States with falsified or fraudulent vaccine credentials. Such a prohibition or other restriction would remain in place until CDC was satisfied that sufficient controls had been established to prevent the reintroduction of DMRVV into the United States, including preventing

the use of falsified or fraudulent vaccine credentials. To implement this provision, this NPRM proposes that HHS/CDC maintain a list of DMRVV-restricted countries. The list would be maintained on CDC's website and updated annually. Amendments to the list of DMRVV-restricted countries would be published as a notice in the *Federal Register*. Under this proposal, CDC may allow the importation of certain categories of dogs from DMRVV-restricted countries, such as service animals or government-owned animals. HHS/CDC solicits comment as to whether such *Federal Register* notices would be sufficient to inform the public.

(ff) Request for issuance of additional fines or penalties.

Under 42 U.S.C. 268(b), CBP and Coast Guard officers may aid in the enforcement of HHS/CDC's quarantine rules and regulations. HHS/CDC is proposing to add a paragraph recognizing that HHS/CDC may request that CBP pursue enforcement actions using CBP's existing authorities under 19 U.S.C. 1592 and 19 U.S.C. 1595a against importers, brokers, or carriers who violate HHS/CDC's dog and cat importation requirements. This provision does not create new authority. Its purpose is to inform the public of actions that CDC may take to request CBP assistance in enforcing HHS/CDC's dog and cat importation requirements. HHS/CDC stresses that it does not administer Title 19, and decisions regarding whether to pursue enforcement actions under Title 19 would be entirely at the discretion of DHS/CBP and subject to its policies and procedures.

V. Alternatives Considered

In developing this NPRM, HHS/CDC considered more and less restrictive policy alternatives. The provisions included in the NPRM were determined to minimize the cost and burden of the proposed regulatory provisions while protecting and reducing risks to the public's health. To reduce the costs associated with the provisions of the NPRM, many proposed

requirements only apply to dogs imported from DMRVV high-risk countries, and some apply only to dogs vaccinated outside the United States imported from DMRVV high-risk countries.

Table 4 summarizes alternatives to selected proposed requirements expected to be associated with most of the monetized costs and benefits for this NPRM (if finalized as proposed) relative to the current status quo. A semi-quantitative analysis of the costs and benefits is available in Section F of an Appendix found in the Supplemental Materials tab of the docket.

Table 4. Summary table of important changes to regulatory requirements based on the provisions of this NPRM and alternatives considered				
NPRM requirement (proposed)	Current requirements¹¹⁸ (baseline)	Option 1-more restrictive	Option 2-less restrictive	Justification
<p>Proposed 71.51(f)</p> <p>Dogs must be at least six months of age to be imported from a DMRVV high-risk country</p> <p>Dogs must be at least six months of age to arrive via aircraft regardless of country origin</p> <p>Only three or fewer dogs less than six months of age may be imported at land ports by an importer/owner (per calendar year). Dogs that have been in DMRVV high-risk countries are not eligible</p>	<p>DMRVV High-risk countries: Dogs must be at least four months of age (based on the earliest age at which a dog could be considered fully vaccinated against rabies)</p> <p>No requirement for DMRVV-free or DMRVV low-risk countries since rabies vaccination documentation is not currently required for these dogs</p>	<p>Dogs must be at least six months of age regardless of country of origin or type of conveyance</p>	<p>Dogs must be at least four months of age to arrive via aircraft regardless of country of origin, which is the youngest age a dog may be considered fully vaccinated against rabies.</p> <p>No limit to the number of dogs that may be imported at land ports</p>	<p>The increased age requirement will improve health and safety for dogs being transported and result in fewer public health investigations of dogs found to be ill or to have died during air travel. The 6-month versus 4-month age requirement will also make it easier to estimate the age of dogs based on examination of their teeth. This age requirement will also improve alignment with USDA import requirements (7 CFR 2148) for</p>

¹¹⁸ The current requirements do not take account of the temporary suspension of dogs from DMRVV high-risk countries, because it is a temporary measure.

Table 4. Summary table of important changes to regulatory requirements based on the provisions of this NPRM and alternatives considered

NPRM requirement (proposed)	Current requirements¹¹⁸ (baseline)	Option 1-more restrictive	Option 2-less restrictive	Justification
to arrive at land ports.				dogs imported for resale.
Proposed section 71.51(g) All dogs must have a microchip regardless of country of origin	No dog-identification requirement other than a description on the rabies vaccination documentation	All dogs must be implanted with microchips <u>and</u> have tattoos for identification purposes	Either no identification requirement <u>or</u> allow use of tattoos or other dog-identifying technology instead of requiring microchips	This requirement is needed to confirm that the arriving dogs match their paperwork because CDC has documented a dramatic increase in the number of dogs arriving with falsified rabies vaccination documentation . The microchip requirement will allow for matching microchip information (obtained by scanning the dog) with the microchip number documented on the dog's proof of rabies vaccination.
Proposed section 71.51(h) Require importers to submit advance data for each dog via a CDC-approved system	No requirement for dog importers to submit data with CDC and no requirement for airlines to create a bill of lading	Require importers to use the more complicated and costly CBP formal entry requirements	Only require dogs from DMRVV high-risk countries to submit data via a CDC-approved system and require airlines	This requirement will help Federal agencies detect dogs that move from DMRVV high-risk to DMRVV low-

Table 4. Summary table of important changes to regulatory requirements based on the provisions of this NPRM and alternatives considered

NPRM requirement (proposed)	Current requirements¹¹⁸ (baseline)	Option 1-more restrictive	Option 2-less restrictive	Justification
and require airlines to create bill of lading for all live dog imports	for all live dog imports		to create a bill of lading for all live dog imports	risk countries to avoid U.S. requirements. This requirement will also support Federal agencies' targeting of interventions for dogs arriving from countries presenting significant risks to human or animal health.
Proposed 71.51 (t) Require standardized rabies vaccination information using a CDC form: <i>Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States</i> Form for dogs originating in the United States and wanting to re-enter the U.S. after traveling to	Rabies vaccine certificates are required for dogs imported from DMRVV high-risk countries and do not need to be entered into a standardized form or certified by an Official Government Veterinarian	Require <i>Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States</i> form be certified by a USDA Official Veterinarian for all dogs leaving the U.S. with planned re-entry into the U.S.	Require veterinarians to fill out the <i>Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States</i> Form, but do not require certification by an Official Government Veterinarian	At present, the information on rabies vaccination documents is not standardized; different formats are used in different countries and even within the U.S. Lack of a standardized format may lead to dogs from DMRVV high-risk countries arriving at a U.S. port with rabies vaccination documentation s that does not align with current CDC requirements

Table 4. Summary table of important changes to regulatory requirements based on the provisions of this NPRM and alternatives considered

NPRM requirement (proposed)	Current requirements¹¹⁸ (baseline)	Option 1-more restrictive	Option 2-less restrictive	Justification
a DMRVV high-risk country				and subsequent entry denials. This provision will also align the United States with import/export requirements commonly required in other countries.
Proposed 71.51(k) Requirement for veterinary examination and revaccination against rabies at a CDC-registered Animal Care Facility for foreign-vaccinated dogs from DMRVV high-risk countries, no requirement for dogs imported from DMRVV-free or DMRVV low-risk countries or U.S.-vaccinated dogs from DMRVV high-risk countries if U.S.-vaccinated dogs are healthy and meet all	No follow-up examination or revaccination required	Require veterinary examination and revaccination for all dogs imported from DMRVV high-risk countries, including dogs with valid U.S.-issued rabies vaccinations s	In lieu of requiring follow-up at a CDC-registered Animal Care Facility, allow dogs imported from DMRVV high-risk countries that were vaccinated outside the United States to visit any licensed U.S. veterinarian for examination and revaccination	This process will better align U.S. requirements with existing requirements of other DMRVV-free countries. This requirement for veterinary examination and revaccination will reduce the risk of dogs potentially infecting people or wildlife with DMRVV and potentially other zoonotic diseases or diseases which impact livestock in the United States.

Table 4. Summary table of important changes to regulatory requirements based on the provisions of this NPRM and alternatives considered

NPRM requirement (proposed)	Current requirements ¹¹⁸ (baseline)	Option 1-more restrictive	Option 2-less restrictive	Justification
<p>other requirements</p> <p>The laboratory testing requirements in proposed 71.51(k)(4)(v) are addressed separately below.</p>				
<p>Proposed 71.51(k)(4)</p> <p>Foreign-vaccinated dogs from DMRVV high-risk countries must have serologic test results from a CDC-approved laboratory with a waiting period, or such time period as specified in CDC technical instructions, before entry or be quarantined for 28 days after revaccination with a USDA-licensed rabies vaccine</p>	<p>No laboratory testing requirement for dog imports from any country</p>	<p>Serologic test from a CDC-approved laboratory with a longer, e.g., 90-day waiting period before entry for dogs vaccinated outside the United States and arriving from DMRVV high-risk countries or all dogs imported from DMRVV high-risk countries require serologic test results</p>	<p>Allow serologic test results for dogs imported from DMRVV high-risk countries with foreign-issued rabies vaccinations from any laboratory (i.e., not limited to CDC-approved laboratories)</p>	<p>This laboratory testing provision will better align U.S. requirements with existing requirements of other DMRVV-free countries that require laboratory confirmation because rabies vaccination documentation alone is considered insufficient as proof of rabies immunity. However, this requirement is still less restrictive than many DMRVV-free countries because there is no serologic test requirement for U.S.-vaccinated dogs.</p>

Table 4. Summary table of important changes to regulatory requirements based on the provisions of this NPRM and alternatives considered

NPRM requirement (proposed)	Current requirements¹¹⁸ (baseline)	Option 1-more restrictive	Option 2-less restrictive	Justification
<p>Proposed 71.51(b)</p> <p>U.S.-vaccinated dogs imported from DMRVV high-risk countries must enter through one of 18 U.S. airports with a CDC quarantine station. Foreign-vaccinated dogs from DMRVV high-risk countries must arrive at a U.S. port with a CDC-registered Animal Care Facility. Such facilities must have an active custodial bond and a FIRMS code issued by CBP, and a USDA intermediate handlers license. Five U.S. ports currently have facilities that meet this standard.</p>	No U.S. port requirement	For all dogs from DMRVV high-risk countries, limit entry to U.S. port with CDC-registered Animal Care Facilities. Five U.S. ports currently have facilities that meet this standard.	Allow foreign-vaccinated dogs imported from DMRVV high-risk countries to enter at any U.S. port with a CDC quarantine station and allow U.S.-vaccinated dogs from any country to enter at any U.S. port	<p>This requirement will ensure dogs denied entry or placed on hold have safe housing locations available and/or CDC oversight. This will reduce the risk that dogs pending or denied entry will be placed in cargo warehouses or other unsafe locations while awaiting CDC determination or return to their countries of origin. This would ensure appropriate veterinary follow up for foreign-vaccinated dogs from DMRVV high-risk countries.</p>

VI. Required Regulatory Analyses

A. Executive Orders 12866 and 13563

Under Executive Order 12866 (EO 12866), Regulatory Planning and Review (58 FR 51735, October 4, 1993), HHS/CDC is required to determine whether this regulatory action would be “significant” and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. EO 12866, as amended by Executive Order 14094, defines “significant regulatory action” as an action that is likely to result in a rule:

- Having an annual effect on the economy of \$200 million or more (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities;
- Creating a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially altering the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- Raising legal or policy issues for which centralized review would meaningfully further the President’s priorities, or the principles set forth in EO 12866, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

OMB’s Office of Information and Regulatory Affairs has determined that this rulemaking is “significant”.

The provisions of this NPRM (if finalized as proposed) are not likely to have an annual effect on the economy of \$200 million or more, although there is considerable uncertainty around the number of dogs imported at baseline, including the number of dogs imported from DMRVV high-risk countries. HHS/CDC conducted an analysis to estimate the costs and benefits

of the proposed provisions of this NPRM relative to a baseline without any change in requirements. To conduct this analysis, CDC assumed the NPRM would be finalized as proposed. HHS/CDC requests public comment on costs associated with these changes to importers, airlines, and State and local health departments to improve the accuracy of cost and benefit estimates. More details on the assumptions used to develop this analysis are included in an Appendix found in the Supplemental Materials tab of the docket, including more specific solicitations for public comment.

The economic baseline is based on the provisions included in the existing 42 CFR 71.51. The baseline analysis does not incorporate the impact of the temporary suspension of dogs imported from DMRVV high-risk countries that has been in effect since July 14, 2021.¹¹⁹ The economic baseline does not account for the temporary suspension but does account for a change to the definition of rabies-free country published in 2019.¹²⁰ This baseline is used as a comparator to assess the impact of the provisions of the NPRM if finalized as proposed.

The provisions of this NPRM (if finalized as proposed) would address the market inefficiency in which dog importers do not consider the potential detrimental impacts to the public's health that may result from the importation of ill dogs, especially dogs infected with DMRVV. Regulation at the Federal level is necessary to address the risk of unhealthy dog imports upon entry to the United States. Federal action allows risks to be addressed prior to dogs' arrival in the United States. The provisions of this NPRM (if finalized as proposed) are expected to affect the following categories of interested parties and implementing partners:

- Importers of dogs from countries that are DMRVV-free or at low risk for DMRVV;

¹¹⁹ On June 14, 2021, CDC published the "Notice of Temporary Suspension of Dogs Entering the United States from High-Risk Rabies Countries." Through this notice, CDC informed the public that, effective July 14, 2021, it was temporarily suspending the importation of dogs from: countries classified by CDC as high risk for DMRVV; AND countries that are NOT at high risk if the dogs have been in high-risk countries during the previous six months. *See* 86 Fed. Reg. 32041 (June 16, 2021). The suspension was extended effective June 10, 2022. *See* 87 Fed. Reg. 33158 (June 1, 2022).

¹²⁰ HHS/CDC. Guidance Regarding Agency Interpretation of "Rabies-Free" as It Relates to the Importation of Dogs Into the United States. 84 Fed. Reg. 724 (Jan. 31, 2019).

- Importers of dogs from countries that are at high risk of DMRVV;
- Airlines and other carriers;
- CBP;
- CDC;
- USDA; and
- State and local public health and animal health departments.

As discussed above, the changes proposed in the NPRM incorporate different requirements depending on whether dogs are imported from DMRVV high-risk countries compared to countries that are DMRVV-free or DMRVV low-risk. Proposed requirements for dogs from DMRVV high-risk countries are further differentiated depending on whether imported dogs have received their rabies vaccines in the United States or in another country. Dogs imported from DMRVV high-risk countries would have to arrive at one of five airports with a CDC-registered Animal Care Facility (foreign-vaccinated dogs) or at one of 18 airports with a CDC quarantine station (U.S.-vaccinated dogs). Importers of foreign-vaccinated dogs from DMRVV high-risk countries would make reservations with a CDC-registered Animal Care Facility for a veterinary examination and revaccination prior to arrival. As part of the proposed entry requirements in the NPRM (if finalized as proposed), importers would either agree to a 28-day quarantine period for the dog or submit samples of the dog's blood to a CDC-approved laboratory for serologic testing to demonstrate immunity to rabies virus. CDC assumes that most importers would choose serologic testing in lieu of the quarantine period. All importers of dogs from DMRVV high-risk countries would submit the *CDC Import Certification of Rabies Vaccination and Microchip Required for All Live Dog Importations into the United States* Form or *Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States* Form, which require certification by an Official Government Veterinarian. However, dogs imported from DMRVV-free or DMRVV low-risk countries do not require evaluation at CDC-registered Animal Care Facilities and are eligible to arrive at any U.S. port. In lieu of the *CDC*

Import Certification of Rabies Vaccination and Microchip Required for All Live Dog

Importations into the United States Form or Certification of U.S.-issued Rabies Vaccination for

Live Dog Re-entry into the United States Form, importers may provide proof that the dogs have only been in DMRVV-free or DMRVV low-risk countries during the six months prior to arriving in the United States (i.e., to demonstrate the dog had not been in a high-risk country).

All dog imports arriving on aircraft conveyances, regardless of whether they arrive from countries that are DMRVV-free or at low- or high-risk for DMRVV, are subject to a six-month minimum age requirement. Dog imports arriving at land ports are only subject to the six-month minimum age requirement if an importer needs to import three or more dogs younger than six months of age in a calendar year. In addition, all dogs would need to be implanted with microchips for identification purposes (if the NPRM is finalized as proposed). All dogs, regardless of country of origin, would be listed on a bill of lading by the airline, if entering the U.S. via air. All importers of dogs arriving at an air, land, or seaport would have to submit a *CDC Import Submission Form* to CDC via a CDC-approved system prior to the dog's departure from the foreign country. The form would need to be presented to the airline or other carrier prior to boarding and upon arrival in the United States.

The annualized and present value estimates of monetized costs and benefits over the 10-year period from 2023 through 2032 using three percent and seven percent discount rates are summarized in Tables 5 and 6. The annualized, monetized costs (2020 USD) of the provisions in the NPRM (if finalized as proposed) are estimated to be \$29 million (range: \$7.8 to \$88 million) using a three percent discount rate, and the results were almost unchanged using a seven percent discount rate. Most monetized costs are expected to be incurred by importers (84 percent for the most likely estimate). The estimated monetized costs are expected to be less for importers of dogs from DMRVV-free or DMRVV low-risk countries compared to importers of dogs from DMRVV high-risk countries. The proposed provisions estimated to result in the greatest increase in costs for importers of dogs imported from DMRVV-free countries were associated with the

additional costs associated with the minimum age, and with the microchip requirements, and completing the new *CDC Import Submission Form*.

The provisions estimated to result in the greatest increase in costs for importers of dogs from DMRVV high-risk countries were associated with the requirements regarding use of a CDC-registered Animal Care Facility for foreign-vaccinated dogs from DMRVV high-risk countries in proposed section 71.51(k). Other costs included: (1) laboratory testing, (2) an expected reduction in the number of dogs imported from DMRVV high-risk countries, (3) the need for some travelers to re-route travel to an airport with a CDC quarantine station or airport with a CDC-registered Animal Care Facility, and (4) the costs with providing a *CDC Import Certification of Rabies Vaccination and Microchip Required for All Live Dog Importations into the United States* Form or *Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States* Form (certified by an Official Government Veterinarian). Airlines are expected to incur the greatest costs among carriers and their costs are estimated to comprise about 8.7 percent of the estimated annualized, monetized costs, with most of their costs associated with ensuring that all transported dogs comply with the bill of lading requirements of the NPRM (if finalized as proposed) and a reduction in the number of dogs transported. HHS/CDC was unable to estimate costs from other types of carriers of dogs arriving by land or sea and welcomes public comment on their potential costs. CDC is estimated to incur about 6.9 percent of the annualized, monetized costs (most likely estimate) associated with the provisions of this NPRM (if finalized as proposed). Most CDC costs would be associated with the oversight of animal care facilities and laboratory proficiency testing programs for dogs imported from high-risk countries. CBP is expected to incur about 0.5 percent of the annualized costs (most likely estimate) associated with the provisions of this NPRM (if finalized as proposed). Most CBP costs would result from training personnel to implement the proposed requirements.

The annualized monetized benefits of the provisions in the NPRM (if finalized as proposed) are estimated to be about \$1.9 million (range: \$0.80 to \$4.0 million) using a three

percent or seven percent discount rate, with most of the benefits accruing to importers (46 percent of the most likely estimates) and to CBP (33 percent of the most likely estimates). Some of the benefits estimated for both importers and CBP would result from reduced time spent on screening dogs from high-risk countries at U.S. ports. The amount of time required per dog at U.S. ports would be reduced because it is assumed that the CDC standardized vaccination forms would be easier to review compared to non-standardized documentation for dogs arriving from DMRVV high-risk countries. The provisions in this NPRM (if finalized as proposed) are also estimated to reduce the number of dogs denied entry or arriving ill or dead, with benefits estimated for importers, airlines, CBP, and CDC.

The wide range between the lower-bound and upper-bound cost and benefit estimates demonstrates that there is considerable uncertainty in these results. More details on the input parameters and assumptions used to generate these estimates may be found in the Appendix under the Supplemental Materials tab of the docket. At present, the number of dogs imported into the United States is neither accurately nor completely tracked by any data system, and the uncertainty in the cost and benefit estimates reflect uncertainty in both the total number of dogs imported and the number of dogs imported from DMRVV high-risk countries, as well as the cost of the new requirements included in the NPRM (if finalized as proposed). The net annualized, monetized costs (total cost estimate – total benefit estimate) are estimated to be about \$26 million per year (range: \$6.9 to \$83 million) using a three percent discount rate.

Table 5. Annualized, monetized costs and benefits summary table (in 2020 million dollars, over a 10-year time horizon relative to baseline, three percent or seven percent discount rate)				Source (RIA Section)
	Most Likely Estimate	Lower bound	Upper bound	
Annualized, monetized benefits (reduced costs)				
Three percent discount rate				
Importer benefits	\$0.89	\$0.37	\$1.8	B1, B2, B3
Airline benefits	\$0.18	\$0.038	\$0.59	B4
DHS/CBP benefits	\$0.65	\$0.30	\$0.95	B5

Table 5. Annualized, monetized costs and benefits summary table (in 2020 million dollars, over a 10-year time horizon relative to baseline, three percent or seven percent discount rate)				Source (RIA Section)
	Most Likely Estimate	Lower bound	Upper bound	
HHS/CDC benefits	\$0.22	\$0.090	\$0.59	B6
State and local health department benefits	\$0.05	\$0.0	\$0.022	B7
Total benefits (A1)	\$1.9	\$0.8	\$4.0	
Seven percent discount rate				
Importer benefits	\$0.89	\$0.37	\$1.8	B1, B2, B3
Airline benefits	\$0.18	\$0.038	\$0.59	B4
DHS/CBP benefits	\$0.65	\$0.30	\$0.95	B5
HHS/CDC benefits	\$0.22	\$0.090	\$0.59	B6
State and local health department benefits	\$0.005	\$0.0	\$0.022	B7
Total benefits (A2)	\$1.9	\$0.80	\$4.0	
Quantified, but unmonetized, benefits	The response costs associated with a dog imported while infected with DMRVV were estimated to be about \$320,000, ranging from \$220,000 to \$520,000. The requirements in the NPRM (if finalized as proposed) reduce the risk of imported dogs arriving with DMRVV, and the costs associated with rabies response activities will decrease.			C1
Qualitative (unquantified) benefits	With each importation of a dog infected with DMRVV, there is a risk that a person may become infected and die or that DMRVV may be re-introduced in the U.S. wildlife population, which could dramatically increase costs relative to the public health response cost summarized above. In addition, by obtaining high-quality data on the number of dogs imported by country, CDC and other Federal agencies, including USDA, will improve preparedness for outbreaks of new and emerging infectious disease threats to humans (e.g., DMRVV) and animals (e.g., African swine fever). The provisions of the NPRM (if finalized as proposed) will also ensure that dogs that are denied entry or arrive ill will receive the veterinary care needed to protect their health and safety.			D1
Annualized, monetized costs				
Three percent discount rate				
Importer costs	\$23.8	\$5.2	\$79.1	B1, B2, B3
Airline costs	\$2.5	\$1.0	\$5.2	B4

Table 5. Annualized, monetized costs and benefits summary table (in 2020 million dollars, over a 10-year time horizon relative to baseline, three percent or seven percent discount rate)				Source (RIA Section)
	Most Likely Estimate	Lower bound	Upper bound	
DHS/CBP costs	\$0.1	\$0.05	\$0.3	B5
HHS/CDC costs	\$1.9	\$1.4	\$2.5	B6
Total costs (B1)	\$28.3	\$7.7	\$87.1	
Seven percent discount rate				
Importer costs	\$23.9	\$5.3	\$79.6	B1, B2, B3
Airline costs	\$2.5	\$1.0	\$5.2	B4
DHS/CBP costs	\$0.2	\$0.06	\$0.4	B5
HHS/CDC costs	\$2.0	\$1.4	\$2.6	B6
Total costs (B2)	\$28.6	\$7.8	\$87.8	
Quantified, but unmonetized, costs	Not applicable			C2
Qualitative (unquantified) costs	CDC would monitor countries and may suspend entry of dogs from countries with repeated instances of dogs with falsified or fraudulent rabies vaccination documentation. The lost value of these imports would impact some U.S. businesses and dog purchasers. In addition, the duration of any suspensions for these countries is highly uncertain and may be ended in the event of improvement of those countries' dog export controls. CDC is proposing the authority to issue orders to revoke a carrier's or importer's permission to transport live dogs and cats if either has endangered the public's health; however, CDC does not have any plans to suspend any carriers or importers at this time. Owners of dogs that undergo a 28-day quarantine period may suffer qualitative costs from being separated from their dogs during quarantine.			D2
Net annualized costs				
Total (three percent discount rate), (B1) - (A1)	\$26.4	\$6.9	\$83.1	
Total (seven percent discount rate), (B1) - (A1)	\$26.6	\$7.0	\$83.8	

The present value of the estimated monetized cost over a 10-year period for the provisions in the NPRM (if finalized as proposed) is estimated to be \$240 million (range: \$65 to \$740 million) using a three percent discount or \$200 million (range: \$53 to \$610 million) using a seven percent discount rate. The present value of monetized benefits over a 10-year period of the provisions in the NPRM (if finalized as proposed) is estimated at \$17 million (range: \$6.9 to \$34 million) using a three percent discount rate or \$14 million (range: \$5.7 to \$28 million) using a seven percent discount rate. The net annualized monetized cost (total costs – total benefits) is estimated at \$230 million per year (range: \$58 to \$700 million) using a three percent discount rate and \$190 million per year (range: \$48 to \$580 million) using a seven percent discount rate.

Table 6. Present value of costs and benefits summary table (in 2020 million dollars, over a 10-year time horizon relative to baseline, three percent or seven percent discount rate)				
	Most Likely Estimate	Lower bound	Upper bound	Source (RIA Section)
<u>Present value of monetized benefits (reduced costs)</u>				
Three percent discount rate				
Importer benefits	\$7.6	\$3.2	\$16	B1, B2, B3
Airline benefits	\$1.5	\$0.32	\$5.0	B4
DHS/CBP benefits	\$5.5	\$2.6	\$8.1	B5
HHS/CDC benefits	\$1.9	\$0.77	\$5.0	B6
State and local health department benefits	\$0.042	\$0.0	\$0.19	B7
Total benefits (A)	\$17	\$6.9	\$34	
Seven percent discount rate				
Importer benefits	\$6.3	\$2.6	\$13	B1, B2, B3
Airline benefits	\$1.2	\$0.27	\$4.1	B4
DHS/CBP benefits	\$4.6	\$2.1	\$6.7	B5
HHS/CDC benefits	\$1.6	\$0.63	\$4.1	B6
State and local health department benefits	\$0.034	\$0.0	\$0.16	B7
Total benefits	\$14	\$5.7	\$28	
Quantified, but unmonetized, benefits	The response costs associated with a dog imported while infected with DMRVV were estimated to be about \$320,000, ranging from \$220,000 to \$520,000. The requirements in the NPRM (if finalized as proposed) reduce the risk of imported dogs arriving with DMRVV, and the costs associated with rabies response activities will decrease.			C1

Table 6. Present value of costs and benefits summary table (in 2020 million dollars, over a 10-year time horizon relative to baseline, three percent or seven percent discount rate)

	Most Likely Estimate	Lower bound	Upper bound	Source (RIA Section)
Qualitative (unquantified) benefits	With each importation of a dog infected with DMRVV, there is a risk that a person may become infected and die or that DMRVV may be re-introduced in the U.S. wildlife population, which could dramatically increase costs relative to the public health response cost summarized above. In addition, by obtaining high-quality data on the number of dogs imported by country, CDC and other Federal agencies, including USDA, will improve preparedness for outbreaks of new and emerging infectious disease threats to humans (e.g., DMRVV) and animals (e.g., African swine fever). The provisions of the NPRM (if finalized as proposed) will also ensure that dogs that are denied entry or arrive ill will receive the veterinary care needed to protect their health and safety.			D1
Present value of monetized costs				
three percent discount rate				
Importer costs	\$203	\$45	\$675	B1, B2, B3
Airline costs	\$21	\$8	\$41	B4
DHS/CBP costs	\$1.1	\$0.4	\$2.6	B5
CDC-costs	\$17	\$11	\$18	B6
Total costs (B)	\$242	\$64	\$737	
Seven percent discount rate				
Importer costs	\$168	\$37	\$559	B1, B2, B3
Airline costs	\$17	\$6.6	\$33	B4
DHS/CBP costs	\$1.1	\$0.4	\$2.4	B5
CDC costs	\$14	\$9.3	\$14	B6
Total costs	\$200	\$53	\$608	
Quantified, but unmonetized, costs	Not applicable			C2
Qualitative (unquantified) costs	CDC would monitor countries and may suspend entry of dogs from countries with repeated instances of dogs with falsified or fraudulent vaccine credentials or invalid rabies vaccination documentation. The lost value of these imports would impact some U.S. businesses and dog purchasers. In addition, the duration of any suspensions for these countries is highly uncertain and may be ended in the event of improvement of those countries' dog export controls. CDC is			D2

Table 6. Present value of costs and benefits summary table (in 2020 million dollars, over a 10-year time horizon relative to baseline, three percent or seven percent discount rate)				
	Most Likely Estimate	Lower bound	Upper bound	Source (RIA Section)
	proposing the authority to issue orders to revoke a carrier’s or importer’s permission to transport live dogs and cats if either has endangered the public’s health; however, CDC does not have any plans to suspend any carriers or importers at this time. Owners of dogs that undergo a 28-day quarantine period may suffer qualitative costs from being separated from their dogs during quarantine.			
Net annualized costs				
Total (three percent discount rate), (B1) - (A1)	\$225	\$58	\$702	
Total (seven percent discount rate), (B1) - (A1)	\$187	\$48	\$581	

The United States was declared DMRVV-free in 2007. Importing dogs from DMRVV high-risk countries involves a significant public health risk. The proposed provisions of this NPRM (if finalized as proposed) would better align U.S. dog importation requirements with those of other countries that have been declared DMRVV-free. Further, the serologic testing requirements are consistent with recommendations in the WOAHH Terrestrial Manual for dogs imported from DMRVV high-risk countries to DMRVV-free countries.¹²¹ One DMRVV-infected dog may cause transmission to humans, domestic pets, livestock, or wildlife. The average cost per importation of a DMRVV-infected dog was estimated to be \$320,000 (range: \$220,000 to \$520,000) to conduct public health investigations and administer rabies PEP to exposed persons.

¹²¹ WOAHH Terrestrial Animal Health Code. Chapter 5.11. Available at: Access online: WOAHH - World Organisation for Animal Health https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=0&htmlfile=chapitre_certif_rabies.htm

Historically, CDC's has denied entry to approximately 200 dogs annually due to fraudulent, incomplete, or inaccurate paperwork.¹²² However, between January 2020 and July 2021 (i.e., during the COVID-19 pandemic, prior to the temporary suspension), CDC documented more than 1000 instances of incomplete, inadequate, or fraudulent rabies vaccination certificates for dogs arriving from DMRVV high-risk countries.¹²³ The diversion of public health resources globally to COVID-19 response activities has contributed to a lapse in canine rabies vaccination efforts and a related increase in the prevalence of dogs infected with DMRVV in some high-risk countries. The combination of an increasing number of dogs imported without adequate documentation of rabies vaccination,¹²⁴ in addition to the potential increase in the prevalence of DMRVV in high-risk countries,¹²⁵ would increase the risk of importation of dogs that are infected with DMRVV. This combination of factors would increase the likelihood of DMRVV-importation events relative to the time-period before the COVID-19 pandemic.

CDC is unable to predict future trends with or without the proposed provisions included in this NPRM to estimate how many dogs infected with DMRVV may be imported. Two rabid dog imports (both from Iran) have been reported in Canada within a seven-month period (specifically July 2021 and January 2022) at around the same time the United States implemented a temporary suspension of dogs imported from DMRVV high-risk countries. Prior to these two imports, Canada had not reported a dog infected with DMRVV since the 1960s.¹²⁶ Given the limited number of reported dogs with DMRVV, this observation may be indicative of

¹²² Centers for Disease Control and Prevention (2021). Quarantine Activity Reporting System (version 4.9.8.8.2.2A). Dog Importation data, 2010-2019. Accessed October 1, 2022.

¹²³ Pieracci, E., Williams, C., Wallace, R., Kalapura, C., Brown, C. U.S. dog importations during the COVID-19 pandemic: Do we have an erupting problem? *PLoS ONE*, 16(9), e0254287. doi: 10.1371/journal.pone.0254287.

¹²⁴ Centers for Disease Control and Prevention. Quarantine Activity Reporting System (version 4.9.8.8.2.2A). Dog importation data, 2018-2020. Accessed: 15 February 2021.

¹²⁵ A Kunkel, Jeon S, Haim, Dilius CJP, Crowdis K, Meltzer MI, Wallace R. (2021) The urgency of resuming disrupted dog rabies vaccination campaigns: a modeling and cost-effectiveness analysis. *Scientific Reports*; 11:12476. <https://doi.org/10.1038/s41598-021-92067-5>.

¹²⁶ *Outbreak News Today* (Feb. 10, 2022) Rabies case reported in Toronto in a dog imported from Iran. <http://outbreaknewstoday.com/rabies-case-reported-in-toronto-in-a-dog-imported-from-iran-46958>. Accessed: February 14, 2022.

a higher risk for dogs imported from DMRVV high-risk countries during the COVID-19 pandemic or could be anomalous occurrences in Canada. However, the provisions included in the NPRM (if finalized as proposed) is expected to substantively reduce the risk of importation of dogs infected with DMRVV relative to baseline.

The primary public health benefit of this NPRM (if finalized as proposed) is the reduced risk that a dog infected with DMRVV will be imported from a high-risk country. Using the most likely estimates of the net monetized cost estimate (\$26.4 million) and the most likely estimate of the potential benefit of averting the importation of one dog with DMRVV from a high-risk country (\$320,000), it is possible to calculate the change in the number of imported dogs infected with DMRVV if the provisions of the NPRM are finalized as proposed relative to the baseline such that the benefit would equal cost. The net cost (\$26.4 million) divided by the cost per importation (\$320,000) suggests that the provisions of the NPRM (if finalized as proposed) relative to baseline would have to avert the importation of 82 dogs infected with DMRVV for the benefit to exceed the cost. This would require an increase in the number of dogs imported into the United States while infected with DMRVV, which could only occur because of widespread failures of rabies control programs in multiple countries. However, this analysis does not consider the potential for fatal rabies cases in people or the risk of reintroduction of DMRVV in the United States, as analyzed below.

The above estimate of the cost of an importation of a dog with DMRVV does not account for the worst-case outcomes, which include (1) transmission of rabies to a person who dies from the disease, or (2) ongoing transmission to other domestic and wildlife species in the United States. The cost of re-introduction could be especially high if DMRVV spreads to other species of U.S. wildlife. Re-establishment of DMRVV in the United States could result in costly efforts over several years to eliminate the virus again. Both worst-case outcomes may be more likely to occur after the COVID-19 pandemic because public health resources were diverted to COVID-19 response activities and disruptions in rabies control programs in high-risk countries.

Disruptions to rabies control programs in DMRVV high-risk countries may contribute to elevated risks even as the COVID-19 pandemic wanes.

Human deaths from rabies continue to occur in the United States after exposure to wild animals; however, no U.S. resident has died after exposure to an imported dog with DMRVV in at least 20 years. CDC uses the value of statistical life (VSL) to assign a value to interventions that can result in mortality risk reductions. For fatal cases, HHS recommends the use of the value of statistical life to estimate the potential benefits of averted deaths, an estimate of \$11.6 million in 2020 USD and a range of \$5.5 to \$17.7 million.¹²⁷ However, CDC is unable to estimate the potential magnitude of the mortality risk reduction associated with the proposed rule. Based on the median VSL, the provisions of the NPRM (if finalized as proposed) would need to help avert three or more human deaths per year for the benefits to exceed costs (or an average of 2.3 deaths per year over multiple years).

Efforts to eliminate DMRVV if re-established in the United States would also prove costly. A previous campaign to eliminate domestic dog-coyote rabies virus variant jointly with gray fox (Texas fox) rabies virus variant in Texas over the period from 1995 through 2003 cost \$34 million,^{128,129} or \$55 million in 2022 USD. The costs to contain any reintroduction would depend on the time-period before the reintroduction was realized, the wildlife species in which DMRVV was transmitted, and the geographic area over which reintroduction occurs. The above estimate is limited to the cost of rabies vaccination programs for targeted wildlife and does not include the costs to administer PEP to any persons exposed after the reintroduction has been

¹²⁷ U.S. Department of Health and Human Services, 2016. Office of the Assistant Secretary for Planning and Evaluation. Guidelines for Regulatory Impact Analysis. https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf. Accessed: April 20, 2020.

¹²⁸ TJ Sidwa et al. (2005) Evaluation of oral rabies vaccination programs for control of rabies epizootics in coyotes and gray foxes: 1995-2003. *Journal of the American Veterinary Medicine Association*; 227(5):785-92.

¹²⁹ R.T. Sterner et al. (2009) Tactics and Economics of Wildlife Oral Rabies Vaccination, Canada and the United States. *Emerging Infectious Diseases*; 15(8), 1176-1184.

identified. Human deaths from DMRVV could increase following the re-introduction of DMRVV to the United States as the risk of exposure would increase.

The provisions of the NPRM (if finalized as proposed) would also ensure that dogs that are denied admission or arrive ill will be housed appropriately and receive the veterinary care needed to protect their health and safety. This will reduce the likelihood that dogs may be left in unsafe conditions in cargo warehouses for extended periods of time (i.e., longer than six hours) with the potential to expose workers who are not trained to handle live animals safely.¹³⁰

Under the current baseline, the number of dogs imported into the United States is neither accurately nor completely tracked. The more comprehensive data collection proposed in this NPRM through the *CDC Import Submission Form* would benefit public health investigations and enable better and more timely contact tracing of all animals exposed to an imported dog with DMRVV. The current lack of data also inhibits the Federal government's ability to target interventions for dogs imported from specific countries. The collection of data from the *CDC Import Submission Form* as proposed in this NPRM may also benefit other agencies such as USDA/APHIS that may want to regulate dog imports based on the risk of introduction of diseases that may affect U.S. livestock. For example, in 2021, APHIS regulated importers of dogs for resale based on whether the dogs were imported from countries where African swine fever exists.¹³¹ The potential economic benefits of reducing the risk of the importation of African swine fever could be significant. For example, a recent African swine fever outbreak in China was estimated to have total economic losses equivalent to 0.78 percent of China's gross domestic product in 2019.¹³² The requirement in the NPRM (if finalized as proposed) to report all dogs to

¹³⁰ <https://www.cbsnews.com/chicago/news/dog-dies-at-ohare-airport-warehouse-17-others-saved-after-being-left-without-food-or-water-for-3-days/>

¹³¹ Animal and Plant Health Inspection Service (Aug. 4, 2021) USDA Announces Requirements for Importing Dogs from Countries Affected with African Swine Fever. https://www.aphis.usda.gov/aphis/newsroom/news/sa_by_date/sa-2021/asf-dog-imports. Accessed: 05 February 2022.

¹³² Shibing You, Tingyi Liu, Miao Zhang, Xue Zhao, Yizhe Dong, Bi Wu, Yanzhen Wang, Juan Li, Xinjie Wei and Baofeng Shi (2021) African swine fever outbreaks in China led to gross domestic product and economic losses. *Nature Food*; 2: 802–808.

CDC via a CDC-approved system would reduce the risk of importation of infected dogs from countries with ongoing disease outbreaks that may affect livestock.

Viruses exploiting new host species have led to some of the most devastating disease epidemics, such as influenza, Ebola, and the HIV/AIDS pandemic.¹³³ Viruses continually evolve in their animal hosts. This has been observed in viruses such as avian and swine influenza viruses, constituting a permanent pandemic threat to humans.¹³⁴ Although CDC cannot predict when future zoonotic diseases may emerge or whether future zoonotic diseases may be associated with transmission from dogs to humans, such events remain a possibility. Future dog-mediated zoonotic diseases may pose an acute risk to the public's health because, in contrast to other animal imports, most dogs are imported as pets and will be in close contact with their owners.

During the COVID-19 pandemic a variant of the SARS-CoV-2 virus was detected in mink populations in Europe and entered human populations from this animal host. Between February 18, 2020, and December 15, 2021, 457 mink farms in 12 countries experienced SARS-CoV-2 outbreaks¹³⁵ and mink-to-human transmission of the SARS-CoV-2 virus was documented on mink farms in the Netherlands, Denmark, Poland, and the United States.^{136,137,138} In August and September of 2020, Denmark documented a mink-associated SARS-CoV-2 variant strain found in 12 people, eight of whom had links to the mink farming industry. Due to concerns about transmissibility, immunity, and potential impacts on vaccine efficacy, the Danish government

¹³³ Woolhouse M, Haydon D, Antia R. Emerging pathogens: the epidemiology and evolution of species jumps. *Trends in Ecology & Evolution* 2005; 20 (5): 238-244. <https://doi.org/10.1016/j.tree.2005.02.009>.

¹³⁴ Woolhouse M, Haydon D, Antia R. Emerging pathogens: the epidemiology and evolution of species jumps. *Trends in Ecology & Evolution* 2005; 20 (5): 238-244. <https://doi.org/10.1016/j.tree.2005.02.009>

¹³⁵ Koopmans M. SARS-CoV-2 and the human-animal interface: outbreaks on mink farms. *The Lancet Infectious Diseases* 2021; 21 (1): 18-19.

¹³⁶ Hammer AS, Quaade ML, Rasmussen TB, et al. SARS-CoV-2 Transmission between Mink (Neovison vison) and Humans, Denmark. *Emerg Infect Dis*. 2021 Feb;27(2):547-551. doi: 10.3201/eid2702.203794. Epub 2020 Nov 18. PMID: 33207152; PMCID: PMC7853580.

¹³⁷ Oude Munnink BB, Sikkema RS, Nieuwenhuijse DF, et al. Transmission of SARS-CoV-2 on mink farms between humans and mink and back to humans. *Science*. 2021 Jan 8;371(6525):172-177. doi: 10.1126/science.abe5901. Epub 2020 Nov 10. PMID: 33172935; PMCID: PMC7857398.

¹³⁸ Rabalski L, Kosinki M, Mazur-Panasiuk N, et al. Zoonotic spillover of SARS-CoV-2: mink-adapted virus in humans. Available at: <https://www.biorxiv.org/content/10.1101/2021.03.05.433713v1.full.pdf>.

ordered that all 15-17 million minks in the country be culled. Following a risk assessment of live mink importations from the Western European region to the United States, CDC determined additional regulatory action to prohibit live mink importations was unnecessary due to public health prevention measures taken by mink importers and the low numbers of imported mink. In comparison, CDC would not have the same data available to conduct a risk assessment for dog imports in the event of a future dog-mediated zoonotic disease outbreak because dog imports are neither accurately nor completely tracked in any government data system in the absence of the dog import submission data requirement proposed in this NPRM.

The proposed reporting of dog import volumes by country in an approved CDC import submission data system provides an opportunity to target interventions for dogs imported from specific countries. Such reporting as proposed in 42 CFR 71.51(h) would allow CDC or other Federal agencies to more easily implement preventive measures to mitigate the risk of introductions of new zoonotic diseases targeted to specific countries of concern. The import submission data requirement may also help CDC and other Federal agencies, as well as State and local health departments, retrospectively inspect shipments from specific countries. This would reduce the costs of future interventions; however, CDC is not able to quantify future savings.

The provisions of the NPRM (if finalized as proposed) are expected to reduce the risk of dogs arriving while ill. If an animal arrives in the United States and appears ill or is dead, a public health investigation is required to ensure the ill or dead animal does not present a public health threat. The overall health of an animal can play a significant role in whether it can maintain core body functions (i.e., body temperature regulation and glucose levels) during prolonged flights. Stressed, malnourished, and young animals are more likely to become ill and can transmit communicable diseases that can affect humans;^{139,140} therefore, safety and welfare

¹³⁹ Galanis E et al. Brucellosis and other diseases imported with dogs. *BCMj* 2019; 61 (4): 177-190. Available at: <https://bcmj.org/bccdc/brucellosis-and-other-diseases-imported-dogs>.

¹⁴⁰ Denstedt E. *Echinococcus multilocularis* as an emerging public health threat in Canada: A knowledge synthesis and needs assessment. Accessed: February 28, 2019. Available at: www.ncceh.ca/sites/default/files/Guelph-Denstedt-2017.pdf.

concerns for the transport of dogs have a public health impact that requires a degree of oversight from public health agencies to ensure human and animal health is protected.¹⁴¹

In addition to the unmonetized benefits described above, there may be additional unmonetized costs. CDC plans to monitor countries and may suspend entry of dogs from countries with repeated instances of falsified or fraudulent dog vaccine credentials or invalid rabies vaccination documents. The lost value of imports from DMRVV-restricted countries would impact some U.S. businesses and dog purchasers. However, the duration of any suspensions for these countries is highly uncertain and may be ended in the event of improvement of those countries' export controls.

HHS/CDC is proposing the authority to issue orders to revoke a carrier's permission to transport live dogs and cats if a carrier has endangered the public's health; however, CDC does not have plans to suspend any carriers at this time.

CDC lacks data on the cost to airlines of ensuring that a representative of an airline transporting live dogs into the United States be on-site at the U.S. port and available to coordinate the entry/clearance of the dogs with Federal government officials until all live dogs on an arriving flight into the United States have either been cleared for entry or arrangements have been made to transport the dogs to a CDC-registered Animal Care Facility or other facility (e.g., veterinary clinic or kennel) approved by CDC pending admissibility determination. CDC believes this will only incur additional costs on occasion since airline staff are typically available on-site. However, HHS/CDC requests public comment to provide more data to estimate costs associated with this proposed requirement.

Impact of the NPRM (if Finalized as Proposed) on Dog Import Volumes

¹⁴¹ Pieracci EG, Maskery B, Stauffer K, Gertz A, Brown C. Risk factors for death and illness in dogs imported into the United States, 2010-2018. *Transbound Emerg Dis.* 2022 Mar 15. doi: 10.1111/tbed.14510.

Although the U.S. Government does not precisely track the total number of dogs imported each year, it was previously estimated that approximately 1 million dogs are imported into the United States annually, of which 100,000 dogs are from DMRVV high-risk countries.¹⁴² This estimate was based on information provided by airlines, CBP, and a zoonoses public health study conducted at a U.S.-Mexico land border crossing.¹⁴³

CBP does record, by country, the number of dogs imported with formal entry under Harmonized Tariff Schedule (HTS) code 0106.19.91.20 and HTS Description: Other live animals, other, other, dogs. CDC used these data from CBP to update its estimates of the annual number of imported dogs. The total number of dogs imported into the United States from all countries under this HTS category varied from 25,232 in 2018 to 58,540 in 2020. The number of dogs from DMRVV high-risk countries under this HTS category averaged 16,390 and varied from 9,966 to 24,031 over this three-year period. Over the three-year period, 43,000 dogs on average were imported per year, with about 38 percent arriving from DMRVV high-risk countries. The number of dogs reported under this HTS category does not include dogs imported as checked baggage, hand-carried in airplane cabins, or crossing land borders without formal entry. Thus, the number underestimates the true number of dogs imported into the United States. The fraction of dogs with this HTS code arriving from DMRVV high-risk countries (38 percent) is much greater than the fraction estimated by CBP field staff (15 percent) in a previous data collection.¹⁴⁴ This could result if the composition of dogs imported for resale or adoption under the HTS code is different than the full distribution of imported dogs. In other words, more individuals may travel internationally with their personal pets or relocate to the United States from DMRVV-free or DMRVV low-risk countries. CDC adjusted for the difference in the

¹⁴² HHS/CDC. Guidance Regarding Agency Interpretation of “Rabies-Free” as It Relates to the Importation of Dogs Into the United States. 84 Fed. Reg. 724 (Jan. 31, 2019).

¹⁴³ McQuiston, J.H., et al., Importation of dogs into the United States: risks from rabies and other zoonotic diseases. *Zoonoses Public Health*, 2008. 55(8-10): p. 421-6.

¹⁴⁴ CDC. Guidance Regarding Agency Interpretation of “Rabies-Free” as It Relates to the Importation of Dogs Into the United States. 84 Fed. Reg. 724 (Jan. 31, 2019).

fraction of dogs imported from DMRVV-free or DMRVV low-risk countries based on estimates from CBP field staff of this fraction and then re-estimated the number of imported dogs arriving at airports, as summarized in Section A2 of the Regulatory Impact Analysis.

CDC used previously reported estimates of the number of dogs arriving at the land ports with Canada and Mexico.¹⁴⁵ The updated estimates for dog imports under the baseline are summarized in Table 7. In total, CDC estimated that under the current regulatory baseline, about 800,000 imported dogs would arrive in the United States each year and that about 500 dogs from DMRVV high-risk countries would be denied admission. The number denied entry is based on CDC data from 2020 and the first six months of 2021 prior to the suspension of dog imports from DMRVV high-risk countries. This approach may overestimate the number of dogs denied entry in the future if the COVID-19 pandemic was associated with a significant increase in dogs denied admission due to pandemic-associated factors. Since dog rabies vaccine certificates are not currently required for dogs from DMRVV-free or DMRVV low-risk countries, CDC did not assume any dogs from these countries would be denied admission under the baseline.

Table 7. Estimated annual numbers of dogs imported into the United States under the current regulatory baseline			
	Most likely estimate	Lower bound	Upper bound
Baseline estimate of dog imports			
From DMRVV-free or DMRVV low-risk countries under baseline, total	733,787	619,229	848,344
Airports	371,507	297,205	445,808
Land ports	362,280	322,024	402,536
Canada-U.S. land ports ¹⁴⁶	120,780	96,624	144,936
Mexico-U.S. land ports ¹⁴⁷	241,500	225,400	257,600
Dogs temporarily denied admission	0	0	0
From DMRVV high-risk countries	65,560	32,780	98,340

¹⁴⁵ CDC. Guidance Regarding Agency Interpretation of “Rabies-Free” as It Relates to the Importation of Dogs Into the United States. 84 Fed. Reg. 724 (Jan. 31, 2019).

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

Dogs approved entry with adequate rabies vaccination documentation	65,060	32,480	97,590
Dogs denied admission	500	300	750
Total dog imports at baseline	798,847	651,709	945,934

The provisions of the NPRM (if finalized as proposed) that are expected to reduce the number of dog imports include: (1) age restrictions on air travel for all dogs under six months of age, including dogs from both DMRVV high-risk and DMRVV low-risk countries; (2) restricting the number of dogs under six months of age allowed to enter the United States at land ports to three or fewer; and (3) the additional costs of fulfilling the requirements for follow-up and revaccination at CDC-registered Animal Care Facilities for foreign-vaccinated dogs from DMRVV high-risk countries. At the same time, CDC believes that the number of dogs denied admission and returned to their countries of origin would decrease if the provisions included in the NPRM are finalized as proposed.

The estimated impact of the NPRM (if finalized as proposed) on the number of dog imports is summarized in Table 8. CDC lacks data on what fraction of dogs arriving by air are less than six months old under the baseline. In the absence of this information, CDC assumes five percent (range: three to eight percent) of dogs currently arriving by air are less than six months and would not be eligible to be imported into the United States under the NPRM (if finalized as proposed). CDC also lacks data on the importers who would want to bring in more than three dogs less than six months of age within a calendar year, which would no longer be allowed with the NPRM (if finalized as proposed). CDC notes that these provisions should primarily impact individuals traveling with their personal pets because the importation of dogs for resale or adoption that are less than six months of age is already prohibited by USDA regulations (7 CFR 2148). Another provision of the NPRM (if finalized as proposed) would require importers of dogs from DMRVV low-risk countries to submit written documentation, such as veterinary medical records, documenting that the animal has been in a DMRVV low-risk

or DMRVV-free country for the six months prior to importation into the United States. CDC does not anticipate denying admission to dogs that may arrive from DMRVV low-risk countries without such documentation if the NPRM is finalized as proposed, but there may be delays at U.S. ports while CDC confirms dogs from DMRVV low-risk countries have not been in a DMRVV high-risk country within the previous six months.

CDC assumes that the additional costs associated with importing dogs from DMRVV high-risk countries with foreign-issued rabies vaccination documentation would reduce the number of imports by about 20 percent (range: 10 to 30 percent) if the NPRM is finalized as proposed. In addition, CDC believes the number of dogs from DMRVV high-risk countries that are denied entry will decrease if the provisions of the NPRM are finalized as proposed because CDC will be able to require the use of standardized forms to confirm rabies vaccination and animal care facility follow-up requirements should be clear to importers. Based in part on the number of dogs denied entry during CDC’s temporary suspension, CDC estimated that about 50 dogs from DMRVV high-risk countries would be denied entry under the provisions of the NPRM (if finalized as proposed). Overall, the provisions in the NPRM (if finalized as proposed) are expected to have a small impact on the total number of dogs imported (from about 799,000 at baseline to 770,000 with the provisions of the NPRM in effect and finalized as proposed).

Table 8. Estimated average annual numbers of dog imports by DMRVV risk category and by immunization status			
	Best estimate	Lower bound ^b	Upper bound ^c
Baseline estimate of dog imports			
From rabies-free, DMRVV-free, or DMRVV low-risk countries under previous guidance			
Total	733,787	619,229	848,344
Airports	371,507	297,205	445,808
Land ports	362,280	322,024	402,536
Canada-U.S. land ports ¹⁴⁸	120,780	96,624	144,936

¹⁴⁸ CDC. Guidance Regarding Agency Interpretation of “Rabies-Free” as It Relates to the Importation of Dogs Into the United States. 84 Fed. Reg. 724 (Jan. 31, 2019).

Mexico-U.S. land ports ¹⁴⁹	241,500	225,400	257,600
Dogs denied entry from rabies-free, DMRVV-free, or low-risk	0	0	0
<u>Dogs from countries at high risk of DMRVV</u>			
Total	65,560	32,780	98,340
Dogs approved entry with rabies vaccination documentation	65,060	32,480	97,590
Estimated fraction of imported dogs from DMRVV high-risk countries that are U.S.-vaccinated	50%	65%	35%
Estimated U.S.-vaccinated dogs	32,530	21,112	34,157
Estimated foreign-vaccinated dogs	32,530	11,368	63,434
Dogs denied entry ^a	500	300	750
Total imported dogs ^a	798,847	651,709	945,934
With NPRM (if finalized as proposed)			
From rabies-free, DMRVV-free, or low-risk countries			
Fraction of dogs who are unable to be imported with NPRM (if finalized as proposed) at airports (due to age restrictions)	5%	3%	8%
Airports	352,931	288,289	410,143
Dogs approved entry	352,578	288,145	409,528
Dogs temporarily denied entry	353	144	615
Fraction of dogs unable to be imported with NPRM (if finalized as proposed) at land ports (due to age restrictions)	1.0%	0.5%	1.5%
Land ports	358,657	320,414	396,498
Canada-U.S. land ports	119,572	96,141	142,762
Dogs approved entry	119,453	96,093	142,548
Dogs temporarily denied entry	120	48	214
Mexico-U.S. land ports	239,085	224,273	253,736
Dogs approved entry	238,846	224,161	253,355

¹⁴⁹ *Id.*

Dogs temporarily denied entry	239	112	381
Dogs temporarily denied entry from rabies-free, DMRVV-free, or low-risk (total)	712	304	1,210
<u>Dogs from countries at high risk of DMRVV</u>			
Fraction of dog imports that would not occur under the provisions of the NPRM (if finalized as proposed) due to the higher costs associated with importing foreign-vaccinated dogs from DMRVV high-risk countries	20%	30%	10%
Total	58,554	29,070	91,247
Number of U.S.-vaccinated dogs approved entry	32,530	21,112	34,157
Number of foreign-vaccinated dogs approved entry	25,974	7,928	57,090
Total dogs approved entry	58,504	29,040	91,172
Dogs denied entry and returned to country-of-origin ^a	50	30	75
Total imported dogs (with NPRM, if finalized as proposed) ^a	770,093	637,743	897,813
Total imported dogs (Baseline) ^a	798,847	651,709	945,934
^a Since these dogs are denied entry and returned to their countries of origin, they are not included in the total number of imports			

CDC did not attempt to project future changes to the volume of dogs imported annually because of insufficient data. CDC believed that introducing another factor to project future volumes was not prudent. HHS/CDC requests public comment from airlines on whether the number of imported dogs has increased, decreased, or remained relatively constant in recent years. Such data may be available to airlines if they track the number of dogs transported each year. While CDC observed an increase in the number of dogs arriving with fraudulent paperwork prior to implementing the temporary suspension, this may not correspond to changes in the total number of dogs imported, of which only a small fraction arrive with fraudulent paperwork.

The most likely estimates of the annual monetized costs and benefits for each interested party or implementing partner are summarized in Table 9 over a 10-year period from 2023

through 2032 using the estimated values presented in Sections B1 through B8 of the Appendix found in the Supplemental Materials tab of the docket. The most likely estimate of monetized costs across interested parties is \$39 million in the first year and \$27 million in subsequent years. The most likely estimate of monetized benefits across interested parties was estimated to be \$1.9 million each year.

The annual costs and benefits for importers are split into importers of dogs from DMRVV-free or DMRVV low-risk countries versus importers of dogs from DMRVV high-risk countries. However, it is likely that some importers of dogs from DMRVV high-risk countries may also be importers of dogs from DMRVV-free or low-risk countries. In addition, the provisions of the NPRM (if finalized as proposed) may result in some importers switching from importing dogs from DMRVV high-risk countries to those from DMRVV-free or low-risk countries.

As a percentage of total costs, importers were estimated to incur 79 to 85 percent of the total costs (most likely estimates), with a higher fraction of total costs incurred in the subsequent years after the first year of implementation. Importer costs are approximately 3.8 times greater for dogs imported from DMRVV high-risk countries compared to dogs from DMRVV-free or low-risk countries. In addition, it is important to note that more than 10 times as many dogs are estimated to be imported from DMRVV-free or low-risk countries. Thus, the cost per dog for importers of dogs from DMRVV high-risk countries is significantly greater than for importers of dogs from DMRVV-free or low-risk countries. This is especially true for foreign-vaccinated dogs from DMRVV high-risk countries.

The costs to airlines are expected to comprise 8.0 to 8.8 percent of total costs. Among Federal government agency costs for the provisions included in the NPRM (if finalized as proposed), CBP's additional costs (0.5 to 2.8 percent of the total) are expected to be less than CDC's additional costs (6.2 to 10.4 percent of the total).

Table 9. Most likely estimates of annual monetized costs and benefits by affected party or implementing partner from 2023 - 2032 relative to baseline in 2020 USD							
Year	Importer s of dogs from DMRVV high-risk countries	Importers of dogs from DMRVV -free or low-risk countries	Airline s	Customs and Border Protection	Centers for Disease Control and Preventio n	State/ local public health and animal health department s	Total
Annual monetized costs (million)							
2023	\$24.6	\$6.5	\$3.2	\$1.1	\$4.1	\$0	\$39
2024	\$18.1	\$4.8	\$2.4	\$0.004	\$1.7	\$0	\$27
2025	\$18.1	\$4.8	\$2.4	\$0.004	\$1.7	\$0	\$27
2026	\$18.1	\$4.8	\$2.4	\$0.004	\$1.7	\$0	\$27
2027	\$18.1	\$4.8	\$2.4	\$0.004	\$1.7	\$0	\$27
2028	\$18.1	\$4.8	\$2.4	\$0.004	\$1.7	\$0	\$27
2029	\$18.1	\$4.8	\$2.4	\$0.004	\$1.7	\$0	\$27
2030	\$18.1	\$4.8	\$2.4	\$0.004	\$1.7	\$0	\$27
2031	\$18.1	\$4.8	\$2.4	\$0.004	\$1.7	\$0	\$27
2032	\$18.1	\$4.8	\$2.4	\$0.004	\$1.7	\$0	\$27
Annual monetized benefits (million)							
2023	\$0.81	\$0.088	\$0.18	\$0.65	\$0.22	\$0.0049	\$1.9
2024	\$0.81	\$0.088	\$0.18	\$0.65	\$0.22	\$0.0049	\$1.9
2025	\$0.81	\$0.088	\$0.18	\$0.65	\$0.22	\$0.0049	\$1.9
2026	\$0.81	\$0.088	\$0.18	\$0.65	\$0.22	\$0.0049	\$1.9
2027	\$0.81	\$0.088	\$0.18	\$0.65	\$0.22	\$0.0049	\$1.9
2028	\$0.81	\$0.088	\$0.18	\$0.65	\$0.22	\$0.0049	\$1.9
2029	\$0.81	\$0.088	\$0.18	\$0.65	\$0.22	\$0.0049	\$1.9
2030	\$0.81	\$0.088	\$0.18	\$0.65	\$0.22	\$0.0049	\$1.9
2031	\$0.81	\$0.088	\$0.18	\$0.65	\$0.22	\$0.0049	\$1.9
2032	\$0.81	\$0.088	\$0.18	\$0.65	\$0.22	\$0.0049	\$1.9

The greatest fractions of the most likely estimates of the monetized benefits associated with the provisions in the NPRM (if finalized as proposed) would accrue to importers of dogs from DMRVV high-risk countries (41 percent) and to CBP (33 percent). For both groups, the costs of screening dogs at U.S. ports would be reduced since documentation of rabies vaccination would be standardized. This would result in cost savings for both groups at U.S. ports, although costs for importers to obtain the standardized forms would increase (as documented in the cost estimates). Additional benefits are estimated to accrue to importers of dogs from DMRVV high-

risk countries, airlines, CBP, and CDC from a reduction in the number of dogs denied entry and returned to their countries of origin.

The estimates included in this economic impact analysis are highly uncertain. HHS/CDC requests comments on several parameter estimates and assumptions in the Appendix found in the Supplemental Materials tab of the docket. Specifically, HHS/CDC is requesting comment from the public on the topics listed below:

- Procedures applicable at U.S. land and seaports and whether and how procedures for U.S. land or seaports should differ from procedures for U.S. airports.
- The numbers of dogs imported each year and the numbers of dogs imported from DMRVV high-risk countries. Such data may be available from airline operating data for air imports. Public comment about dogs imported at land or seaports could help to improve estimates.
- The impact of the requirements of this NPRM (if finalized as proposed) to reduce the number of dogs imported from DMRVV high-risk countries.
- The fraction of imported dogs arriving on air conveyances that are less than six months of age.
- The number of importers that bring in more than three dogs at land or seaports that are less than six months of age during a calendar year.
- Data showing whether the number of imported dogs has increased, decreased, or remained relatively constant in recent years. Such data may be available to airlines if they track the number of dogs transported each year.
- The number of dogs imported at one time or as part of one shipment on average and if the requirements of this NPRM (if finalized as proposed) would impact how dogs are imported (e.g., would importers wait to import a larger group of dogs in a single shipment).

- The number of times individuals who travel internationally with their dogs enter the United States each year.
- How this proposed rulemaking would impact the ability of individuals with foreign-vaccinated service dogs to enter the United States.
- How frequently importers of dogs for adoption or resale import dogs (i.e., among businesses that import dogs for commercial purposes, how many shipments are received each year on average). This information would be used to improve CDC's estimate of the number of repeat importers.
- Costs to owners of young dogs who would have to forego international travel with their pets.
- The additional travel costs and travel time associated with re-routing travel through an airport with a CDC quarantine station or an airport with a CDC-registered Animal Care Facility.
- The average cost to return a dog to the country of departure after denial of entry and the cost to importers whose dogs have been denied entry.
- The appropriate range of estimates from airlines for the profit margin per dog imported on international flights.
- The cost to airlines if they were prevented from transporting dogs on flights in the future.
- The cost to CDC-registered Animal Care Facilities to comply with proposed CDC requirements for these facilities.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), agencies are required to analyze regulatory options to minimize the significant economic impact of a rule on small businesses, small governmental units, and small not-for-profit organizations. CDC examined the potential impact of the

provisions of this NPRM (if finalized as proposed) on small entities, including small businesses that may import dogs for commercial purposes as well as airlines that transport dogs internationally. HHS/CDC lacks key data on the number of dogs imported and requests public comment from airlines and small businesses on the number of dogs imported and the impact of the provisions of the NPRM (if finalized as proposed) on their standard practices. In the absence of data on the number of dogs imported, CDC made several assumptions to estimate revenues from small businesses for different categories of businesses that may import dogs and used these revenue estimates to calculate how many dogs could be imported such that the costs associated with the provisions of this NPRM (if finalized as proposed) would be less than two percent of estimated revenues.

Based on these analyses, CDC believes that the only small entities for which this NPRM (if finalized as proposed) would have significant impacts would be those that specialize in importing dogs from DMRVV high-risk countries. The provisions of this NPRM (if finalized as proposed) would not have a significant economic impact on small airlines and probably would not have a significant impact on small entities that import dogs from DMRVV-free or DMRVV low-risk countries. CDC notes that the importation of dogs less than six months of age for resale or adoption in the United States is already prohibited by USDA regulations (7 CFR 2148). Thus, the minimum age requirements in this proposed NPRM (if finalized as proposed) should not impact entities that sell or resell imported dogs but may impact entities that import young dogs for commercial purposes other than resale. The NPRM (if finalized as proposed) does not include provisions that would reduce costs for small entities relative to other categories of importers.

As part of the economic impact analysis, CDC calculated the marginal cost associated with the proposed provisions in the NPRM per dog imported from DMRVV-free or DMRVV low-risk countries (\$9.10, range: \$2.60 to \$25 per imported dog). The marginal cost associated with the proposed provisions in the NPRM per dog imported from DMRVV high-risk countries

was further subdivided between foreign-vaccinated dogs (vaccinated outside the United States) (\$810, range: \$550 to \$1,180) compared to U.S.-vaccinated dogs (\$110, range: \$44 to \$510). These estimates cover the first year of implementation after a final rule is published, assuming the NPRM requirements are finalized as proposed. Marginal costs in the second year and later are estimated to be about 25 percent less per dog compared to the first year of implementation.

The estimates summarized below are subject to a great degree of uncertainty. CDC does not know how many dogs any small individual entity currently imports or the average number of imported dogs across entities. However, based on the relative estimates of annual revenues by type of entity and subdivided by the number of employees, CDC calculated how many dogs each entity could import before this NPRM (if finalized as proposed) would have a significant economic impact on their businesses. HHS/CDC welcomes public comments to improve and refine these estimates.

Small entities that import dogs for commercial purposes

The estimated revenues of small businesses likely to import and resell dogs are summarized in Table 10. Since there are no specific codes in the North American Industry Classification System (NAICS) specific to dog importers, CDC used the codes 115210, 423820, 424990, 485991, 812910, and 813312 to estimate the revenue of the small businesses that may import and resell dogs. The businesses affected by the NPRM (if finalized as proposed) would be a fraction of the firms summarized in Table 10, as CDC does not know how many dog importers are in these categories. Small business status was determined based on either firms' revenue or the numbers of employees, according to the Small Business Association's (SBA) table of small business size standards.¹⁵⁰ The revenue of firms in each business category subdivided by the number of employees was not available. Using annual payroll data from the Statistics of U.S.

¹⁵⁰ SBA, Table of small business size standards. Effective August 19, 2019. <https://www.sba.gov/document/support-table-size-standards>.

Businesses (SUSB),¹⁵¹ CDC estimated the revenue based on the assumption that each firm's payroll expense would be approximately 15 to 30 percent.¹⁵²

Table 10. Estimated revenue of small businesses that may import dogs for commercial purposes, 2020 USD							
NAICS code	Description	Number of employees	Firms	Annual payroll per firm (thousand USD)	Revenue per firm (thousand USD) ^a		
					Lower bound (Payroll/30%)	Upper bound (Payroll/15%)	Most likely estimate (midpoint)
115210	Support Activities for Animal Production	<5	3,633	\$48	\$161	\$321	\$241
		5-9	585	\$181	\$605	\$1,210	\$907
		10-19	238	\$406	\$1,355	\$2,709	\$2,032
		20-99	118	\$1,259	\$4,197	\$8,394	\$6,296
423820	Farm and Garden Machinery and Equipment Merchant Wholesalers	<5	1,808	\$90	\$300	\$599	\$450
		5-9	958	\$308	\$1,026	\$2,053	\$1,539
		10-19	835	\$693	\$2,309	\$4,619	\$3,464
		20-99	820	\$2,094	\$6,980	\$13,960	\$10,470
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	<5	7,068	\$75	\$249	\$499	\$374
		5-9	1,493	\$299	\$996	\$1,992	\$1,494
		10-19	791	\$657	\$2,191	\$4,383	\$3,287
		20-99	670	\$1,755	\$5,850	\$11,700	\$8,775
485991	Special Needs Transportation	<5	1,553	\$55	\$184	\$368	\$276
		5-9	554	\$148	\$493	\$986	\$740
		10-19	500	\$338	\$1,127	\$2,254	\$1,691
		20-99	611	\$1,050	\$3,500	\$6,999	\$5,249
812910	Pet Care (except Veterinary) Services	<5	12,257	\$43	\$142	\$283	\$213
		5-9	4,026	\$140	\$466	\$931	\$698
		10-19	2,580	\$280	\$932	\$1,863	\$1,398
		20-99	1,213	\$663	\$2,210	\$4,421	\$3,316
813312	Environment, Conservation and Wildlife Organizations	<5	3,575	\$75	\$249	\$498	\$373
		5-9	1,262	\$263	\$875	\$1,751	\$1,313
		10-19	922	\$516	\$1,720	\$3,441	\$2,580
		20-99	745	\$1,551	\$5,169	\$10,338	\$7,754
^a Revenue was estimated from the annual payroll reported in the 2019 SUSB Annual Data Tables by Establishment Industry (https://www.census.gov/data/tables/2019/econ/susb/2019-							

¹⁵¹ 2019 SUSB Annual Data Tables by Establishment Industry.

<https://www.census.gov/data/tables/2019/econ/susb/2019-susb-annual.html>.

¹⁵² How to figure the gross percent of payroll. <https://smallbusiness.chron.com/figure-gross-percent-payroll-66395.html>.

susb-annual.html). Estimated were updated to 2020 USD using the Consumer Price Index for All Urban Consumers (CPI-U).

CDC assumes that the costs associated with the proposed provisions of the NPRM (if finalized as proposed) would be significant if the additional costs would exceed two percent of the estimated revenue shown in Table 10 by category. Unless a small entity only specialized in importing dogs for resale or adoption, the costs associated with dog importation would only constitute a portion of each firm's operational costs. Other operational costs by an entity should be unaffected by the proposed provisions included in this NPRM (if finalized as proposed). CDC is unaware of the proportion of dog import costs relative to all the other activities for each type of entity. Thus, CDC was not able to directly estimate the impact of the NPRM (if finalized as proposed) as a fraction of total revenue. Instead, CDC calculated a threshold for each category representing the number of imported dogs at which the cost of the provisions in the NPRM to importers (if finalized as proposed) would begin to exceed two percent of the revenue of firms in each category. To calculate the number of dogs at which point the costs associated with the NPRM (if finalized as proposed) would be likely to exceed two percent of revenue for each category of the firm, the category-specific revenue per firm in Table 10 (most likely estimate, lower bound, and upper bound) were multiplied by 2 percent and then divided by the marginal cost per foreign-vaccinated dog from high-risk countries (\$810, range: \$550 to \$1,180). This was repeated for U.S.-vaccinated dogs from DMRVV high-risk countries (\$110, range: \$44 to \$510) and dogs from DMRVV-free or DMRVV low-risk countries (\$9.10, range: \$2.60 to \$25). The estimated thresholds for the number of imported dogs per firm for each small business category are summarized in Tables 11a and 11b. For example, if a Wildlife Organization (NAICS code 813312) with fewer than five employees import more than ten foreign-vaccinated dogs (most likely NPRM cost estimate and midpoint revenue estimate) from high-risk countries, the costs associated with the NPRM (if finalized as proposed) would be expected to exceed two percent of revenue. For U.S.-vaccinated dogs, the threshold would increase from about ten dog imports to

68 dog imports using the most likely cost estimate and midpoint revenue estimate. This NAICS category may include dog rescue organizations that are likely to work with dogs imported from DMRVV high-risk countries, most or all of which would be foreign-vaccinated. Because the marginal cost estimate per dog imported from DMRVV-free or DMRVV low-risk countries (assuming the NPRM is finalized as proposed) is much less than per dog imported from DMRVV high-risk countries, the threshold numbers of dogs that may be imported from DMRVV-free or DMRVV low-risk countries are much greater than for DMRVV high-risk countries. The values shown in Tables 11a and 11b are estimated by assuming that all dogs imported by each firm are either from DMRVV-free or DMRVV low-risk countries or, alternatively, from DMRVV high-risk countries. Some firms may import dogs from both types of countries, in which case, the threshold values would be in between the two sets of estimates. The difference in costs may also cause some entities to shift from importing dogs from DMRVV high-risk countries to dogs imported from DMRVV-free or DMRVV low-risk countries if the NPRM is finalized as proposed. In this case, for a business with NAICS code of 813312, the estimated threshold number of dogs would increase from ten imported foreign-vaccinated dogs from DMRVV high-risk countries to 823 dogs imported from DMRVV-free or DMRVV low-risk countries (both thresholds calculated using most likely NPRM cost estimate and midpoint revenue estimate). HHS/CDC welcomes public comments from the dog importation industry to improve these threshold estimates.

Table 11a. Estimated threshold for the number of imported dogs from DMRVV high-risk countries per firm at which NPRM costs (if finalized as proposed) would exceed two percent of revenue during the first year of implementation of the proposed requirements							
NAICS code	Number of employees	Foreign-vaccinated dogs from high-risk countries			U.S.-vaccinated dogs from high-risk countries		
		Most likely estimate	Lower bound	Upper bound	Most likely estimate	Lower bound	Upper bound
Marginal NPRM cost per dog (USD, if finalized as proposed)		\$810	\$553	\$1,178	\$110	\$44	\$507
Number of imported dogs per year at which NPRM cost > 2 percent of revenue							
115210,	<5	6	6	6	44	72	13

Support Activities for Animal Production	5-9	23	22	21	164	271	48
	10-19	51	49	46	366	606	106
	20-99						
		156	152	143	1,132	1,876	328
423820, Farm and Garden Machinery and Equipment Merchant Wholesalers	<5	12	11	11	81	134	24
	5-9	38	37	35	277	459	81
	10-19	86	84	79	623	1,032	181
	20-99						
		259	252	237	1,882	3,119	545
424990, Other Miscellaneous Nondurable Goods Merchant Wholesalers	<5	10	9	9	68	112	20
	5-9	37	36	34	269	445	78
	10-19	82	79	75	591	979	172
	20-99						
		217	211	199	1,577	2,614	457
485991, Special Needs Transportation	<5	7	7	7	50	83	15
	5-9	19	18	17	133	221	39
	10-19	42	41	39	304	504	88
	20-99	130	127	119	944	1,564	274
812910, Pet Care (except Veterinary) Services	<5	6	6	5	39	64	12
	5-9	18	17	16	126	208	37
	10-19	35	34	32	252	417	73
	20-99	82	80	75	596	988	173
813312, Environment, Conservation and Wildlife Organizations	<5	10	9	9	68	112	20
	5-9	33	32	30	236	392	69
	10-19	64	62	59	464	769	135
	20-99	192	187	176	1,394	2,310	404

Table 11b. Estimated threshold for the number of imported dogs from DMRVV-free or DMRVV low-risk countries per firm at which NPRM costs (if finalized as proposed) would exceed two percent of revenue during the first year of implementation of the proposed requirements

NAICS code	Number of employees	Foreign-vaccinated dogs from high-risk countries		
		Most likely estimate	Lower bound	Upper bound
Marginal NPRM cost per dog (if finalized as proposed, USD)		\$9.10	\$2.60	\$25
Number of imported dogs per year at which NPRM cost > two percent of revenue				
115210, Support Activities for Animal Production	<5	531	1,257	258
	5-9	1,999	4,736	973
	10-19	4,476	10,605	2,177
	20-99	13,867	32,856	6,744
423820, Farm and Garden Machinery and Equipment	<5	991	2,347	482
	5-9	3,391	8,034	1,649
	10-19	7,630	18,079	3,711
	20-99	23,061	54,641	11,215

Merchant Wholesalers				
424990,	<5	824	1,953	401
Other Miscellaneous	5-9	3,291	7,797	1,601
Nondurable Goods	10-19	7,240	17,155	3,522
Merchant Wholesalers	20-99	19,327	45,794	9,400
485991,	<5	608	1,441	296
Special Needs	5-9	1,630	3,860	793
Transportation	10-19	3,725	8,825	1,812
	20-99	11,562	27,396	5,623
812910,	<5	469	1,110	228
Pet Care (except	5-9	1,539	3,645	749
Veterinary) Services	10-19	3,079	7,294	1,497
	20-99	7,303	17,305	3,552
813312,	<5	823	1,949	401
Environment,	5-9	2,893	6,853	1,407
Conservation and	10-19	5,684	13,468	2,765
Wildlife	20-99	17,078	40,466	8,306
Organizations				

The marginal cost per dog imported (if the NPRM is finalized as proposed) relative to the reported commercial values of imported dogs were estimated using data from CBP for dogs imported under Harmonized Tariff Schedule code 0106.19.91.20, Other live animals, other, other, dogs is shown in Table 12. The estimated ratio of the marginal cost of NPRM requirements (if finalized as proposed) relative to the reported value of the commercially imported dogs from DMRVV-free or DMRVV low-risk countries is 1.2 percent (range: 0.33 percent to 3.2 percent). Based on this ratio, the expected marginal increase in cost per dog imported should not change much for dogs imported from DMRVV-free or low-risk countries.

However, for the foreign-vaccinated dogs imported from DMRVV high-risk countries, the estimated ratio is 227 percent (range: 155 percent to 330 percent). This ratio is much larger both because the marginal cost per dog imported (assuming the NPRM is finalized as proposed) is much greater and because the reported commercial value of dogs imported from DMRVV high-risk countries is lower compared to dogs imported from DMRVV-free or low-risk countries. Since CBP's commercial values of imported dogs only provide a comparison of the estimated marginal cost of the NPRM (if finalized as proposed) to reported commercial value,

these ratios cannot be directly compared to the revenue estimates by firm since the costs associated with dog imports would only be a portion of each firm's operational cost. However, it does provide an estimate of the potential increase in cost per dog imported from either DMRVV-free or low countries or from DMRVV high-risk countries if the NPRM is finalized as proposed. For this analysis, CDC assumes that most of the dogs imported from DMRVV high-risk countries for commercial purposes would have been vaccinated outside the United States.

Table 12. Estimated impact of the NPRM (if finalized as proposed) on the cost per dog imported for commercially imported dogs (2020 USD)			
	Most likely estimate	Lower bound	Upper bound
Importers from DMRVV-free or low-risk countries			
Baseline ^a			
- Total dogs imported (A)	57,860	-	-
- Average commercial value per dog (B)	\$777	-	-
- Total commercial value (C)=(A)×(B)	\$44,957,220	-	-
With NPRM (if finalized as proposed)			
- Estimated marginal NPRM cost per dog imported (if finalized as proposed) (D)	\$9.08	\$2.55	\$24.89
- Total marginal NPRM costs for dogs imported for commercial purposes (if finalized as proposed) (E)=(D)×(A)	\$525,369	\$147,543	\$1,440,135
Estimated ratio of marginal NPRM costs to commercial value of imported dogs (E)/(C)	1.17%	0.33%	3.20%
Importers from high-risk countries of foreign-vaccinated dogs			
Baseline ^a			
- Total dogs imported (F)	43,382	-	-
- Average commercial value per dog (G)	\$357	-	-
- Total commercial value (H)=(F)×(G)	\$15,487,374	-	-
With NPRM (if finalized as proposed)			
- Estimated marginal NPRM costs per dog imported (if finalized as proposed) (I)	\$810	\$553	\$1,178
- Total marginal NPRM costs for dogs imported for commercial purposes (if finalized as proposed) (J)=(I)×(F)	\$35,139,420	\$23,990,246	\$51,103,996

Estimated ratio of marginal NPRM costs to commercial value of imported dogs (J)/(H)	227%	155%	330%
^a Baseline values were based on the data received from CBP, not publicly available (HTS code 0106.19.91.20).			

U.S. Airlines

The provisions of this NPRM (if finalized as proposed) would affect U.S. airlines conducting international flight operations arriving in the United States. Of the 60 U.S. airlines with international flights in 2020, 35 airlines can be identified as small business entities. This is based on the size standard of “fewer than 1,500 employees” from the SBA for small businesses within NAICS Code 481111, Scheduled Passenger Air Transportation, and those within NAICS Code 481211, Nonscheduled Chartered Passenger Air Transportation in 2019.¹⁵³ For the analysis, airline employee counts were estimated from the U.S. Department of Transportation’s Bureau of Transportation Statistics.¹⁵⁴ Monthly average numbers of employees in 2019, including part- and full-time employment, were used for U.S. airlines.

The annual revenue per U.S. airline was estimated based on the 2019 revenue of each airline.¹⁵⁵ Lower-bound and upper-bound estimates were calculated by multiplying by 75 and 125 percent (Table 13). Among the selected 35 airlines, seven had zero U.S. international arrivals in 2019.¹⁵⁶

Table 13. Estimated annual revenue of small business U.S. airlines		
Airline	Total revenue (million USD)	2019 U.S.

¹⁵³ Small Business Association (SBA), Table of small business size standards. Effective August 19, 2019. <https://www.sba.gov/document/support-table-size-standards>. Accessed: February 21, 2022.

¹⁵⁴ Bureau of Transportation Statistics. Air Carrier Financial Reports (Form 41 Financial Data). Air Carrier Financial: Schedule P-1(a) Employees. Bureau of Transportation Statistics. https://www.transtats.bts.gov/DL_SelectFields.asp?gnoyr_VQ=GEF&QO_fu146_anzr=Nv4percent20Pn44vr4percent20Sv0n0pvny Accessed: February 21, 2022.

¹⁵⁵ Bureau of Transportation Statistics. Air Carrier Financial Reports (Form 41 Financial Data). Air Carrier Financial: Schedule P-1.1, and P-1.2 Operating revenues. https://www.transtats.bts.gov/DL_SelectFields.asp?gnoyr_VQ=FMD&QO_fu146_anzr=Nv4percent20Pn44vr4percent20Sv0n0pvny; and https://www.transtats.bts.gov/DL_SelectFields.asp?gnoyr_VQ=FMI&QO_fu146_anzr=Nv4percent20Pn44vr4percent20Sv0n0pvny. Accessed: February 21, 2022.

¹⁵⁶ Air Carriers: T-100 International Market (U.S. Carriers Only) https://www.transtats.bts.gov/DL_SelectFields.asp?gnoyr_VQ=GDJ&QO_fu146_anzr=Nv4percent20Pn44vr45. Accessed: February 21, 2022.

	Most likely estimate	Lower bound	Upper bound	arrivals
1	\$290	\$218	\$363	317
2	\$78	\$58	\$97	279
3	\$112	\$84	\$140	169
4	\$241	\$181	\$301	136
5	\$38	\$28	\$47	116
6	\$44	\$33	\$55	114
7	\$230	\$173	\$288	113
8	\$541	\$406	\$677	111
9	\$218	\$164	\$273	96
10	\$115	\$87	\$144	86
11	\$558	\$419	\$698	80
12	\$1,296	\$972	\$1,620	75
13	\$42	\$31	\$52	73
14	\$52	\$39	\$66	57
15	\$169	\$127	\$212	57
16	\$37	\$28	\$46	55
17	\$104	\$78	\$130	49
18	\$147	\$110	\$183	46
19	\$265	\$199	\$331	45
20	\$7	\$6	\$9	41
21	\$40	\$30	\$50	40
22	\$2	\$1	\$2	31
23	\$105	\$79	\$131	18
24	\$59	\$44	\$74	13
25	\$20	\$15	\$25	12
26	\$19	\$14	\$23	6
27	\$9	\$7	\$12	2
28	\$313	\$235	\$391	1
29	\$12	\$9	\$14	0
30	\$115	\$86	\$143	0
31	\$117	\$88	\$146	0
32	\$13	\$10	\$16	0
33	\$10	\$7	\$12	0
34	\$21	\$16	\$27	0
35	\$19	\$14	\$23	0

The threshold numbers of dogs that may be transported by each airline such that the costs associated with the provisions of this NPRM (if finalized as proposed) to airlines would be less than two percent of annual revenue were estimated using the same methodology as for the dog importers above. However, the annualized marginal cost per dog transported by airlines was only estimated to be about \$6.00 per dog (range: \$3.20 to \$10.30 per dog) if the requirements in the NPRM are finalized as proposed. This was calculated based on the annualized costs to airlines

divided by the number of dogs transported. However, costs were estimated to be higher in the first year of implementation and some airlines may be disproportionately affected if their customers are proportionally more likely to reduce the number of dogs transported to the United States. The estimated number of dogs was calculated by multiplying the revenue per airline in Table 13 by 2 percent and then dividing by the marginal airline cost per dog imported if the NPRM is finalized as proposed. As shown in Table 14, the estimated numbers of dogs that each airline could transport were significantly greater than the number of international passengers reported in 2019 and, in most cases, greater than the total estimated number of dogs estimated to be imported into the United States each year. CDC did not separately estimate marginal costs to airlines for dogs imported from DMRVV-free or DMRVV low-risk countries versus dogs imported from DMRVV high-risk countries. The estimated marginal cost per dog may be higher for airlines to transport dogs imported from DMRVV high-risk countries because dogs from these countries are more likely to be denied entry and abandoned by importers. Thus, marginal costs may be slightly higher for airlines that specialize in travel to DMRVV high-risk countries. However, the general finding still holds that the provisions of this NPRM (if finalized as proposed) should not have a significant impact on airlines.

Table 14. Estimated threshold of the annual number of imported dogs per airline at which the marginal costs of the NPRM (if finalized as proposed) begin to exceed 2 percent of annual revenue				
Airline	Most likely estimate	Lower bound	Upper bound	2019 U.S. arrivals
Marginal NPRM cost per dog (if finalized as proposed)	\$6.00	\$3.20	\$10.30	-
Annual number of transported dogs at which NPRM cost > 2 percent of annual revenue				
1	48,333,333	68,125,000	35,242,718	317
2	13,000,000	18,125,000	9,417,476	279
3	18,666,667	26,250,000	13,592,233	169
4	40,166,667	56,562,500	29,223,301	136
5	6,333,333	8,750,000	4,563,107	116
6	7,333,333	10,312,500	5,339,806	114
7	38,333,333	54,062,500	27,961,165	113

8	90,166,667	126,875,000	65,728,155	111
9	36,333,333	51,250,000	26,504,854	96
10	19,166,667	27,187,500	13,980,583	86
11	93,000,000	130,937,500	67,766,990	80
12	216,000,000	303,750,000	157,281,553	75
13	7,000,000	9,687,500	5,048,544	73
14	8,666,667	12,187,500	6,407,767	57
15	28,166,667	39,687,500	20,582,524	57
16	6,166,667	8,750,000	4,466,019	55
17	17,333,333	24,375,000	12,621,359	49
18	24,500,000	34,375,000	17,766,990	46
19	44,166,667	62,187,500	32,135,922	45
20	1,166,667	1,875,000	873,786	41
21	6,666,667	9,375,000	4,854,369	40
22	333,333	312,500	194,175	31
23	17,500,000	24,687,500	12,718,447	18
24	9,833,333	13,750,000	7,184,466	13
25	3,333,333	4,687,500	2,427,184	12
26	3,166,667	4,375,000	2,233,010	6
27	1,500,000	2,187,500	1,165,049	2
28	52,166,667	73,437,500	37,961,165	1
29	2,000,000	2,812,500	1,359,223	0
30	19,166,667	26,875,000	13,883,495	0
31	19,500,000	27,500,000	14,174,757	0
32	2,166,667	3,125,000	1,553,398	0
33	1,666,667	2,187,500	1,165,049	0
34	3,500,000	5,000,000	2,621,359	0
35	3,166,667	4,375,000	2,233,010	0

C. Paperwork Reduction Act of 1995

HHS/CDC has determined that this NPRM includes proposed information collections and recordkeeping requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). A description of these proposed provisions is given below, with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions,

searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. Comments are invited on the following subjects:

- Whether the proposed collection of information is necessary for the proper performance of the functions of CDC, including whether the information will have practical utility.
- The accuracy of CDC's estimate of the burden of the collection of information.
- Ways to enhance the quality, utility, and clarity of the information to be collected.
- Ways to minimize the burden of the collection of information on respondents, including by using information technology.

Under the PRA, Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each new proposed collection, each proposed extension of an existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a revised data collection as described below.

OMB is particularly interested in comments that will help:

1. Evaluate whether the revised collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other

technological collection techniques or other forms of information technology (e.g., permitting electronic submissions of responses); and,

5. Assess information collection costs.

Proposed Project

Importation Regulations (42 CFR 71 Subpart F) – Revised Information Collection – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This information collection is a revision to OMB Control Number 0920-1383 related to the importation of animals, animal products, and human remains. HHS/CDC is amending the *CDC Import Certification of Rabies Vaccination and Microchip Record* Form and renaming it *CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States* Form. HHS/CDC is instituting a new import submission system that will collect information similar to what is currently approved to be collected for the *Application for Special Exemption for a Permitted Dog Import* form. CDC is also proposing to require per 42 CFR 71.51 that importers of dogs have either a *CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States* Form or a *Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States* Form, which is a form approved under OMB Control No. 0579- 0020, 0036, 0048, 0101, 0156, 0278, and 0432. The *Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States* Form will be revised as part of information collection OMB Control No. 0579- 0020, 0036, 0048, 0101, 0156, 0278, and 0432.

Section 361 of the PHS Act (42 U.S.C. 264) authorizes the Secretary of HHS to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. The existing regulations governing foreign quarantine activities (42 CFR 71) authorize quarantine officers and other personnel to inspect and undertake necessary control measures with respect to conveyances, persons, shipments of animals, articles, and other items to protect the public's health.

CDC regulations govern the importation of animals and animal products capable of causing human disease. Animals that are regulated by CDC include dogs, cats, turtles, nonhuman primates (NHPs), civets, African rodents, and bats. CDC controls the importation of these animals to ensure that these animals, or animal products, being imported into the United States meet CDC regulations. CDC does this through a permitting process for certain animals.

The currently approved form (*Application for Special Exemption for a Permitted Dog Import*) for individuals to apply for a *CDC Dog Import Permit* is an online form that includes a series of questions. It also requires applicants to upload proof of eligibility to import under the current requirements, serology results, a proof of rabies vaccination, and photos of their dog's teeth.

The process for dog importation under the provisions of the NPRM (if finalized as proposed) will require issuing far fewer *CDC Dog Import Permits* compared to the currently approved information collection, since only people seeking approval to import dogs from DMRVV-restricted countries would need to apply. Under the currently approved information collection, importers of foreign-vaccinated dogs from high-risk countries can apply for a *CDC Dog Import Permit* in lieu of making a reservation with a CDC-approved animal care facility. The option to apply for a *CDC Dog Import Permit* for importers of foreign-vaccinated dogs from high-risk countries, however, is not being proposed in this NPRM. At this time, CDC is not including any countries on the DMRVV-restricted countries list; therefore, the annual burden in

the burden table reflects a change in burden hours to zero hours for the *Application for Special Exemption for a Permitted Dog Import* form. The most significant changes to the current information collection will be the requirement to complete a standardized form for U.S.-vaccinated dogs (*Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States*; approved under OMB Control No. 0579- 0020, 0036, 0048, 0101, 0156, 0278, and 0432) or an amended standardized form for foreign-vaccinated dogs (*CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States*) and a new *CDC Import Submission Form*. The *CDC Import Submission Form* will contain similar information to the current *Application for Special Exemption for a Permitted Dog Import* form and is proposed to be required for all dog importations.

The standardized rabies vaccination forms will be completed by the importers' veterinarian to ensure all required information is on the form and signed by a government official. Currently, to be valid, rabies vaccination documentation must include the name and address of the owner; dog's breed, sex, date of birth, color, and markings; microchip number; date of vaccination and vaccine product information, including product expiration date; date the vaccination expires; and name, license number, address, and signature of the veterinarian who administered the vaccination. CDC found that despite these being requirements for importation, many people submitted incomplete rabies vaccination documentation, which both delayed the issuance of the requestor's permit and used staff time for multiple communications with requestors to ensure they obtained complete rabies vaccination documentation. It also meant some requestors made multiple requests to their veterinarian, increasing the time burden on them as well. CDC is attempting to solve this issue by requiring that importers have their veterinarian complete one of the standardized CDC forms that contains all the required information and have it verified by a government official, making the form harder to falsify.

Additionally, CDC proposes to require importers to submit a *CDC Import Submission Form* online via a new CDC import submission system for each dog being imported. Importers

would submit contact information and details about the dog similar to what is currently collected in the *Application for Special Exemption for a Permitted Dog Import* form. The new information that would be collected in this system compared to what is currently approved to be collected in the *Application for Special Exemption for a Permitted Dog Import* form is: whether the submission is a new CDC submission or a change to an existing submission; the method by which someone is traveling to the United States (air, sea, or land); and, if they marked change to an existing submission, an explanation of that change. It would also not require that an importer upload their rabies vaccination documentation.

The burden table below has been updated to reflect the burden hours on veterinarians to complete the rabies vaccination forms and the total amount of time it will take an importer to complete the online import submission form.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Dog Importers with Foreign-vaccinated dogs	<i>CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States</i>	13,671	1	15/60	3,418
Veterinarians for Foreign-vaccinated dogs	<i>CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations</i>	13,671	1	15/60	3,418

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
	<i>into the United States</i>				
Official Government Veterinarian in Exporting Country	<i>CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States</i>	13,671	1	15/60	3,418
Importers of U.S.-vaccinated dogs	<i>Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States</i>	17,121	1	15/60	4,280
Veterinarians for U.S.-vaccinated dogs	<i>Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States</i>	17,121	1	15/60	4,280
Importers of Dogs from DMRVV-restricted Countries	<i>Application for Special Exemption for a Permitted Dog Import</i>	0	0	60/60	0
All dog importers	<i>CDC Import Submission Form</i>	800,000	1	7/60	93,333
Animal Care Facilities	<i>Application</i>	10	1	60/60	10
Total					112,157

D. National Environmental Policy Act (NEPA)

HHS/CDC has determined that amendments to 42 CFR part 71 will not have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is needed.

E. Executive Order 12988: Civil Justice Reform

HHS/CDC has reviewed this rule under Executive Order 12988 on Civil Justice Reform and determines that this NPRM meets the standard in the Executive Order.

F. Executive Order 13132: Federalism

Under Executive Order 13132, if the rulemaking would limit or preempt State, local, or tribal authorities, then a federalism analysis is required. The agency must consult with State, local, and tribal officials to determine whether the rule would have a substantial direct effect on State or local governments, as well as whether it would either preempt State law or impose a substantial direct cost of compliance on them.

HHS/CDC has determined that this NPRM will not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

G. Plain Language Act of 2010

Under 63 Fed. Reg. 31883 (June 10, 1998), Executive Departments and Agencies are required to use plain language in all proposed and final rules. HHS/CDC has attempted to use plain language in this proposed rulemaking to make our intentions and rationale clear and requests input from the public in this regard.

List of Subjects in 71.50, 71.51:

Airline, animal, border, canine rabies virus variant, carrier, cat, communicable diseases, confinement, DMRVV, Director, dog, exemption, importation, importer, microchip, necropsy, permit, public health, quarantine, rabies, rabies vaccination, rabies virus, serologic testing, valid rabies vaccination certificate, zoonotic diseases

For the reasons discussed in the preamble, we propose to amend 42 CFR part 71 as follows:

PART 71 — FOREIGN QUARANTINE

1. The authority citation for part 71 continues to read as follows:

Authority: Secs. 215 and 311 of Public Health Service (PHS) Act. as amended ([42 U.S.C. 216](#), [243](#)); secs. 361–369, PHS Act, as amended ([42 U.S.C. 264–272](#)).

2. Amend § 71.50 by:

a. Adding in alphabetical order to paragraph (b) definitions for “Authorized veterinarian”, “Cat”, “Dog”, “Histopathology”, “In-transit shipment”, “Microchip”, “Necropsy”, and “Official government veterinarian”; and

b. Adding paragraph (c).

The additions read as follows:

§ 71.50 Scope and definitions.

* * * * *

(b) * * *

Authorized veterinarian means an individual who has obtained both an advanced degree and valid license and is authorized to practice animal medicine in the exporting country.

* * * * *

Cat means all domestic cats (*Felis catus*).

* * * * *

Dog means all domestic dogs (*Canis familiaris*).

* * * * *

Histopathology means the study of changes in human or animal tissue caused by disease.

* * * * *

In-transit shipment means a cargo shipment originating in a foreign country that is moved through one or more U.S. ports of entry while transiting through the United States to a third-

country destination. In-transit shipments pass through a U.S. port of entry and a U.S. port of exit, which may be in the same location, or which may involve numerous stopping points.

* * * * *

Microchip means an implanted radio-frequency device placed under the skin of an animal that contains a unique identification tag that meets the International Standards Organization (ISO) compatibility through ISO 11784 or ISO 11785, or similar technologies as approved by the Director.

Necropsy means an animal autopsy in which the cause of death may be determined through the examination and collection of tissues, organs, or bodily fluids post-mortem.

Official government veterinarian means a veterinarian who performs work on behalf of an exporting country's government and can verify the license or credentials of an Authorized Veterinarian.

* * * * *

(c) Any provision of this subpart held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this subpart and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

3. Amend § 71.51:

a. In paragraph (a) by:

i. Adding in alphabetical order definitions for “Animal”, CDC-registered animal care facility”, “CDC import submission form”, “CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States”, “Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States”, and “Conditional release”;

ii. Revising the definition of “Confinement”;

iii. Adding in alphabetical order definitions for “DMRVV”, “DMRVV-free countries”, “DMRVV high-risk countries”, “DMRVV low-risk countries”, “DMRVV-restricted countries”, “Importer”, “SAFE TraQ”, “Serologic testing”, “USDA-accredited veterinarian”, and “USDA official veterinarian”; and

iv. Redesignating paragraphs (1) through (4) in the definition of “Valid rabies vaccination certificate” as paragraphs (i) through (iv);

d. By revising paragraphs (b) through (g); and

e. By adding paragraphs (h) through (ff).

The additions and revisions read as follows:

§ 71.51 Dogs and cats.

(a) * * *

Animal means, for purposes of this section, all domestic cats (*Felis catus*) or domestic dogs (*Canis familiaris*).

* * * * *

CDC-registered animal care facility means a facility registered by CDC for the purpose of providing veterinary care and housing to animals imported into the United States.

CDC import submission form means an OMB-approved declaration submitted to CDC through an online portal that includes the importer’s name and contact information; description of the dog, including microchip number and current photographs of the dog’s face and body; purpose of importation; travel information, including dates of departure and arrival, country of departure, countries visited in the past six months, and U.S. port of entry; and other information as described in CDC technical instructions.

CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States means the OMB-approved form that must be:

- (i) Completed by an authorized veterinarian in the exporting country, which may include an official government veterinarian in the exporting country; and
- (ii) Reviewed and signed by an official government veterinarian in the exporting country attesting that the information listed is true and correct.

Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States means the OMB-approved form that must be completed by a U.S. Department of Agriculture (USDA)-accredited veterinarian and certified by a USDA official veterinarian prior to exporting the dog from the United States in order to demonstrate compliance with admissibility requirements upon returning to the United States.

Conditional release, when applied to an animal, means the temporary release of an animal from the custody of a carrier into the care of a licensed veterinarian approved by the Director for the purpose of receiving emergency medical care or a public health evaluation, pending removal of the animal from the United States. The licensed veterinarian must return animals immediately to the carrier's custody upon the conclusion of such medical care or evaluation for removal from the United States.

Confinement, when applied to an animal, means restriction to a building or other enclosure at a U.S. port or other location approved by the Director, including *en route* to a destination, separate from other animals, and from persons except for contact necessary for its care. If the animal is allowed out of the enclosure, it must be muzzled and kept on a leash.

DMRVV means dog-maintained rabies virus variant and includes any rabies virus variant that is known or suspected to have an enzootic transmission cycle in which dogs are essential for the maintenance of the viral variant. This includes epidemiologic situations in which dogs are the only recognized reservoir species, as well as situations in which dogs and other species (typically wildlife) both play an epidemiologically relevant role in maintaining enzootic transmission.

DMRVV-free countries mean countries determined by the Director as not having DMRVV present based on internationally accepted standards.

DMRVV high-risk countries mean countries determined by the Director as having high risk for DMRVV transmission based on factors such as the presence and geographic distribution of the virus or low quality of or low confidence in rabies surveillance systems or dog vaccination programs.

DMRVV low-risk countries mean countries determined by the Director as having low risk for DMRVV transmission based on factors such as the virus being limited to a localized area, adequacy of surveillance and dog vaccination programs to prevent further geographic distribution of the virus, and the virus being in a controlled status with the country or countries heading toward eventual DMRVV-free status.

DMRVV-restricted countries means countries for which the export of dogs into the United States has been prohibited or otherwise restricted based on the countries' export of dogs infected with DMRVV to any other countries within a timeframe determined by the Director or based on the countries' lacking adequate controls, as determined by the Director, to monitor and prevent the export of dogs to the United States with falsified or fraudulent vaccine credentials, invalid rabies vaccination documentation, or other fraudulent, inaccurate, or invalid importation documents.

* * * * *

Importer for purposes of this section means any person importing or attempting to import an animal into the United States, including an owner or a person acting on behalf of an importer, such as a broker registered with U.S. Customs and Border Protection (CBP). Individuals compensated or hired to transport animals must have a valid USDA license or registration.

* * * * *

SAFE TraQ means the System for Animal Facilities Electronic Tracking of Quarantine or other system as approved by the Director for tracking the quarantine of animals approved for admission into the United States.

Serologic testing, when applied to an imported animal, means a rabies antibody titration test performed by a CDC-approved rabies laboratory using a CDC-approved technique. The serology sample must be drawn, submitted and tested in accordance with CDC technical instructions. The current list of CDC-approved laboratories is available online on CDC's website. CDC will update its website as needed.

USDA-accredited veterinarian shall have the same definition as accredited veterinarian under 9 CFR 160.1.

USDA official veterinarian means the Animal and Plant Health Inspection Service (APHIS) veterinarian who is assigned by the USDA Administrator to supervise and perform the official work of APHIS in any U.S. State or several U.S. States.

* * * * *

(b) *Authorized U.S. airports for dogs and cats.* (1) Cats may arrive at and be admitted into the United States through any U.S. airport.

(2) Dogs arriving to the United States from DMRVV low-risk or DMRVV-free countries that have not been in any DMRVV high-risk country within the last six months may arrive at and be admitted into the United States through any U.S. airport.

(3) Dogs that have been in a DMRVV high-risk country within the last six months and were vaccinated against rabies in the United States must arrive at and may only be admitted through a U.S. airport with a CDC quarantine station.

(4) Dogs that have been in a DMRVV high-risk country within the last six months and were vaccinated against rabies in a foreign country must arrive at and may only be admitted through a U.S. airport with a CDC quarantine station and a CDC-registered Animal Care Facility.

(5) Dogs that have been in a DMRVV high-risk country within the last six months that arrive at an unauthorized U.S. airport shall be denied admission and returned to their countries of departure via air pursuant to paragraph (v) of this section.

(6) The current list of U.S. airports with CDC quarantine stations is available on CDC's website. CDC also maintains a list of U.S. airports with CDC-registered Animal Care Facilities on its website. CDC will update these lists as needed.

(c) *Authorized U.S. land ports for dogs and cats.* (1) Cats may arrive at and be admitted into the United States through any U.S. land port.

(2) Dogs arriving to the United States from DMRVV low-risk or DMRVV-free countries that have not been in any DMRVV high-risk country within the last six months may arrive at and be admitted into the United States through any U.S. land port.

(3) Dogs that have been in a DMRVV high-risk country within the last six months are not authorized to enter the United States through any U.S. land port and shall be denied admission into the United States.

(d) *Authorized U.S. seaports for dogs and cats.* (1) Cats may arrive at and be admitted into the United States through any U.S. seaport.

(2) Dogs arriving to the United States from DMRVV low-risk or DMRVV-free countries that have not been in any DMRVV high-risk country within the last six months may arrive at and be admitted into the United States through any U.S. seaport.

(3) Dogs that have been in a DMRVV high-risk country within the last six months are not authorized to enter the United States through any U.S. seaport and shall be denied admission into the United States.

(4) Notwithstanding paragraph (d)(3) of this section, a dog meeting the definition of a "service animal" under 14 CFR 382.3 that has been in a DMRVV high-risk country within the last six months may be admitted through a U.S. seaport if:

(i) The dog is accompanied by an “individual with a disability” as defined under 14 CFR 382.3 and the dog does work or performs tasks that are directly related to the individual's disability; and

(ii) The dog was vaccinated against rabies in the United States and is accompanied by a valid Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States form; or

(iii) The dog was vaccinated against rabies in a foreign country and is accompanied by a valid foreign-issued CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States form and a valid serologic titer from a CDC-approved laboratory.

(e) *Limitation on U.S. ports for dogs and cats.* The Director may limit the times, U.S. ports, or conditions under which dogs or cats may arrive at and be admitted to the United States based on an importer's or carrier's failure to comply with the provisions of this section or as needed to protect the public's health. If the Director determines a limitation is required, the Director will notify importers or carriers in writing of the specific times, U.S. ports, or conditions under which dogs and cats may be permitted to arrive at and be admitted to the United States.

(f) *Age requirement for all dogs.* All dogs presented for admission into the United States must be at least six (6) months old at the time of arrival into the United States. However, an importer may present for admission up to three (3) individual dogs within the same calendar year below the age of six (6) months if the dogs are arriving in the United States by land from Canada or Mexico and the dogs have not been in a DMRVV high-risk or DMRVV-restricted country since birth.

(g) *Microchip requirements for all dogs.* (1) All dogs presented for admission into the United States must have a microchip implanted prior to arrival at the U.S. port.

(2) The microchip number must be documented on the CDC Import Certification of Rabies Vaccination and Microchip Required for All Live Dog Importations into the United

States form or the Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States form or documented on the veterinary health records of the dog if arriving from a DMRVV low-risk or DMRVV-free country. The microchip number must also be documented on the CDC import submission form.

(3) The importer must consent to the scanning of the dog's microchip upon arrival by CDC quarantine public health officers or their representatives.

(4) Dogs arriving in the United States without a microchip, with a microchip that cannot be detected, with a microchip that does not match the accompanying documentation, or if the importer refuses to have the dogs' microchip scanned, may be denied admission and returned to the country of departure pursuant to paragraph (v) of this section.

(h) *CDC Import Submission Form for all dogs.* (1) All importers of dogs into the United States must submit a *CDC Import Submission Form* to CDC via a CDC-registered system prior to the dogs' arrival. This includes accompanied or unaccompanied dogs arriving by air, land, and sea regardless of whether arriving as cargo, checked-baggage, or hand-carried baggage.

(2) Dogs that arrive without a complete and accurate CDC import submission form filed prior to arrival may be denied admission and returned to the country of departure pursuant to paragraph (v) of this section, regardless of the value of the shipment.

(3) Dogs arriving by air without a complete and accurate CDC import submission form may be held on a space-available basis for up to 24 hours after arrival in the care of a CDC-registered animal care facility or a licensed veterinarian if the animal care facility cannot house the dog until the form is filed or if the dog arrives at an airport without a CDC-registered animal care facility. The importer (or airline if the importer abandons the animal) is responsible for making all necessary arrangements with a CDC-registered animal care facility or a veterinary clinic if the animal care facility cannot house the dog or is not available at the airport, including arranging transportation to the facility. The airline may require reimbursement from an importer for any associated costs incurred by the airline on the importer's behalf.

(4) Dogs arriving by sea without a complete and accurate CDC import submission form may be held onboard the vessel until the form is filed. The vessel's owner or operator may require reimbursement from an importer for any associated costs incurred by the vessel on the importer's behalf.

(5) Dogs arriving by land without a complete and accurate CDC import submission form shall be denied admission and returned immediately to the dogs' country of departure, but such denial does not prevent the importer from reapplying for admission of the dogs after the form is filed.

(6) A receipt confirming submission of the form to CDC must accompany all dogs departing foreign locations for travel to the United States. For dogs departing from foreign airports to the United States, the airline must deny boarding to dogs unless the importer has presented this receipt prior to boarding.

(7) Airlines are required to create a bill of lading for all dogs arriving in the United States prior to arrival. This includes dogs transported as cargo, checked-baggage, or hand-carried baggage.

(8) Dogs arriving by air for which a bill of lading has not been filed prior to arrival in the United States may be denied admission and returned to the country of departure pursuant to paragraph (v) of this section.

(i) *Inspection requirements for admission of all dogs and cats.* (1) All animals arriving at a U.S. port shall be inspected upon arrival, and only those animals that show no signs of communicable disease as defined in 42 CFR 71.1 shall be admitted into the United States.

(2) All animals presented for admission into the United States may be subject to additional examination and disease surveillance screening for the purpose of communicable disease surveillance. Ill animals may be required to undergo additional diagnostic testing prior to release of the animal; such testing is not considered surveillance screening.

(3) The Director may require confinement of an animal and examination by a veterinarian when necessary to determine whether the animal is admissible into the United States, for instance, if dental examination would assist in determining the animal's age.

(4) Importers who refuse to consent to inspection, examination, or disease surveillance screening of the animal upon arrival may have the animal denied admission and returned to its country of departure pursuant to paragraph (v) of this section.

(j) *Examination by a USDA-accredited veterinarian and confinement of exposed dogs and cats or those that appear unhealthy.* (1) If an animal, upon inspection, does not appear to be in good health (e.g., it has symptoms such as emaciation, lesions of the skin, discharge of the eyes or nose, coughing, sneezing, nervous system disturbances, inability to stand or walk, difficulty breathing, jaundice, vomiting, or diarrhea), or appears healthy but, during shipment, may have been exposed to a sick or dead animal (including an animal other than a dog or cat) suspected of having a communicable disease, the Director may require prompt confinement and veterinary examination.

(2) In the case of animals that appear unhealthy or those that were potentially exposed and arriving by air or sea, the Director may require the airline or vessel's master or operator to arrange for a licensed veterinarian to examine the animal and give or arrange for any tests or treatment indicated. In the case of animals that appear unhealthy or those that were potentially exposed and arriving by land, the Director may deny admission, but such denial does not prevent the importer from reapplying for admission after providing the Director with satisfactory evidence that a licensed veterinarian has examined the animal and administered any tests or treatment as needed.

(3) Carriers shall maintain a record of sickness of animals occurring while en route to the United States and shall submit the record upon arrival to the CDC quarantine station with jurisdiction for the U.S. port.

(4) Animals that become sick while en route or on arrival shall be separated from other animals (including an animal other than a dog or cat) as soon as the sickness is discovered and shall be held in confinement pending any necessary examination as determined by the Director.

(5) Airlines (in the case of arrivals by air) or a vessel's master or operator (in the case of arrivals by sea) shall immediately arrange for medical evaluation by a licensed veterinarian of any animals that arrive sick and for transportation as needed to a facility for confinement or medical evaluation of any sick animals. In the case of sick animals arriving by land, the Director may deny admission, but such denial does not prevent the importer from reapplying for admission after providing the Director with satisfactory evidence of confinement (as needed) and examination by a licensed veterinarian.

(6) The Director will consider the findings of the examination and tests in determining whether the animal may have a communicable disease.

(7) The airline or vessel's master or operator shall arrange for confinement at a CDC-registered animal care facility or CDC-approved veterinary clinic which, in the judgment of the Director, affords protection against transmission of any communicable disease and suitable housing in accordance with the Animal Welfare Act (7 U.S.C. 2131 *et seq.*, as may be amended).

(8) The importer shall bear the expenses of confinement, examination, tests, and treatment under this paragraph. If an importer fails to arrange for or pay for such expenses or cooperate with any CDC-mandated public health evaluations, then the animal will be considered abandoned, and the carrier shall assume financial responsibility pursuant to paragraph (z) of this section.

(9) Confinement shall be subject to conditions specified by the Director to protect the public's health.

(10) CDC may request that CBP conditionally release animals in need of medical evaluation or treatment. Animals eligible for conditional release shall remain under the legal custody of the carrier or CDC-registered animal care facility for the purpose of receiving

emergency veterinary medical care or examination. Such animals must be returned immediately to a CDC-registered animal care facility or other CDC-approved kennel or veterinary facility (if a CDC-registered animal care facility is not available) once medical treatment is no longer required or upon request by either CDC or CBP.

(11) If an importer (or carrier if the animal is abandoned by the importer) opts to have an animal euthanatized (e.g., under circumstances where the animal is fatally ill or injured), the importer or carrier shall promptly communicate this decision to CDC and CBP in writing and prior to euthanasia. Euthanasia does not relieve importers or carriers of the obligation to arrange and pay for testing and necropsy required by CDC.

(k) *Veterinary examination and revaccination against rabies at a CDC-registered animal care facility for foreign-vaccinated dogs.* (1) All dogs arriving from DMRVV high-risk countries that do not have a valid certification of U.S.-issued rabies vaccination for live dog re-entry into the United States form shall undergo veterinary examination and revaccination against rabies at a CDC-registered animal care facility upon arrival.

(2) The importer is responsible for making all arrangements relating to the examination, revaccination, and quarantine of dogs with a CDC-registered animal care facility prior to arrival in the United States. The costs of examination, vaccination, or quarantine shall be borne by the importer and not at the government's expense.

(3) Importers are required to present to airlines documentation confirming their reservation at a CDC-registered animal care facility prior to their dogs boarding a flight to the United States. Airlines must deny boarding to dogs if the importer fails to present such documentation.

(4) Prior to granting a reservation, CDC-registered animal care facilities must ensure they have received the following:

(i) The completed CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States form;

(ii) Serologic test results collected in accordance with CDC's technical instruction from a CDC-approved laboratory (if applicable);

(iii) Photos of the dog's teeth to assist with age verification;

(iv) The travel itinerary for the dog confirming that the dog will only be arriving at a U.S. airport with a CDC quarantine station and a CDC-registered animal care facility and will not be arriving at any other U.S. port; and

(v) A receipt confirming submission of the CDC import submission form.

(5) Airlines must deny boarding to any foreign-vaccinated dog for which the importer has not presented a receipt confirming submission of the CDC import submission form and proof of a reservation at a CDC-registered animal care facility, or that is being presented for travel to an unauthorized U.S. airport.

(6) The airline shall arrange for dogs to be transported by a CBP-bonded transporter to a CDC-registered animal care facility immediately upon arrival at the U.S. airport.

(7) The dog shall remain in the custody of the CDC-registered animal care facility until the following requirements are met:

(i) Veterinary health examination by a USDA-accredited veterinarian for signs of illness. All illnesses must be documented in SAFE TraQ. CDC will review these illness case reports and determine admissibility prior to the animal's release. Suspected or confirmed zoonotic or foreign animal diseases, including the presence of ecto-parasites (i.e., ticks and fleas), must be reported to CDC, USDA, the State or county public health veterinarian, and the State veterinarian prior to release of the animal.

(ii) Vaccination against rabies with a USDA-licensed rabies vaccine that is administered by a USDA-accredited veterinarian.

(iii) Confirmation of microchip number.

(iv) Confirmation of age through dental examination by a USDA-accredited veterinarian.

(v) Verification of adequate rabies serologic test from a CDC-approved laboratory.

Serologic tests must be drawn within a timeframe as specified in CDC technical instructions.

Dogs that arrive without an adequate rabies serologic test results from a CDC-approved laboratory, or with a serologic test result drawn outside the acceptable timeframe, or with serologic test results outside acceptable parameters, shall be housed, at the CDC-registered animal care facility for a 28-day quarantine period following administration of the USDA-licensed rabies vaccine.

(l) *Registration or renewal of CDC-registered animal care facilities.* (1) Before housing any live dog imported into the United States, a facility must register with and receive written approval from the Director to function as a CDC-registered animal care facility. Applications and all required documents must be submitted to cdcanimalimports@cdc.gov.

(2) To register or to renew a registration certificate, a facility must submit the following documents to CDC:

(i) A completed registration/application form;

(ii) A statement of intent that describes the number and types of animals the facility can house at one time, including the number of animals that can be housed in the quarantine area;

(iii) Written standard operating procedures that include all elements required in paragraphs (k) through (q) of this section;

(iv) A copy of all Federal, State, or local registrations, licenses, and/or permits; a facility must have a USDA Class H intermediate handlers license (and any additional class licenses or registrations as deemed appropriate by USDA) and a CBP Facilities Information and Resource Management System (FIRMS) code.

(v) A self-certification signed by the owner or manager of the CDC-registered Animal Care Facility stating that the facility is in compliance and agrees to continue to comply with the regulations in this section.

(3) Upon receiving the documentation required by this section, the Director will review the application and either grant or deny the application for registration as a CDC-registered Animal Care Facility. Applications that are denied may be appealed under paragraph (r) of this section.

(i) Before issuing a registration, the Director may inspect any animal health record, facility, vehicle, or equipment to be used in management, examination, and clearance of imported animals. Thereafter, animal health records, facilities, vehicles, and equipment used in importing animals may be inspected during annual site inspection visits or when otherwise needed to protect the public's health.

(ii) Unless revoked in accordance with paragraph (r) of this section, a registration certificate issued under this section is effective for two years beginning from the date CDC issues the registration certificate.

(iii) A CDC-registered animal care facility must apply to CDC for renewal of the registration certificate not less than 60 days and not more than 90 days before the existing registration expires.

(4) The Director may deny an application to register, renew, or reinstate a facility as a CDC-registered animal care facility if the registrant has had a previous registration revoked in accordance with paragraph (r) of this section within the last five years.

(5) All CDC-registered animal care facilities must comply with the requirements of paragraphs (k) through (q) of this section.

(m) *Record-keeping requirements at CDC-registered animal care facilities.* (1) A CDC-registered animal care facility must retain records regarding each imported animal for three years after the distribution or transfer of the animal. Each record must include:

- (i) The bill of lading for each shipment;
- (ii) The name, address, phone number, and email address of the importer and owner (if different from the importer);

- (iii) The number of animals in each shipment;
- (iv) The identity of each animal in each shipment, including name, microchip number, date of birth, sex, breed, and coloring;
- (v) The airline, flight number, date of arrival, and port of arrival of each shipment;
- (vi) Veterinary medical records for each animal, including:
 - (A) CDC import certification of rabies vaccination and microchip required for live dog importations into the United States form and rabies serology obtained before arrival in the United States (if applicable);
 - (B) The USDA-licensed rabies vaccine administered upon arrival;
 - (C) Veterinary examination records upon arrival and while in quarantine;
 - (D) Rabies serology performed while in quarantine in the United States (if applicable);
 - (E) All diagnostic test results performed during quarantine; and
 - (F) Necropsy reports for imported animals that die while in the care of the CDC-registered animal care facility.

(2) A CDC-registered animal care facility must maintain these records electronically in SAFE TraQ.

- (i) Copies of all records must be entered directly into or uploaded into SAFE TraQ;
- (ii) Records must be uploaded and complete prior to the animal's release from the facility; and
- (iii) CDC will audit records remotely as needed and in-person during the annual site inspection visit(s) at the facility.

(n) *Worker protection plan and personal protective equipment (PPE).* (1) A CDC-registered Animal Care Facility must establish and maintain a worker protection plan with standards comparable to those in the National Institute for Occupational Safety and Health (NIOSH) Veterinary Safety and Health guidelines and the National Association of Public Health

Veterinarians (NASPHV) Compendium of Veterinary Standard Precautions for Zoonotic Disease
Prevention in Veterinary Personnel.

(2) In addition to complying with the requirements of this section, a facility must comply with all relevant Federal and State requirements relating to occupational health and safety.

(3) Rabies pre-exposure prophylaxis is required for workers handling imported animals in rabies quarantine.

(4) Post-exposure procedures that provide potentially exposed workers with direct and rapid access to a medical consultant.

(5) Procedures for documenting the frequency of worker training, including for those working in the quarantine area.

(6) As part of the worker protection plan, a facility must establish, implement, and maintain hazard evaluation and worker communication procedures that include the following:

(i) Descriptions of the known zoonotic disease and injury hazards associated with handling animals;

(ii) The need for PPE when handling animals and training in the proper use of PPE, including re-training and reinforcement of appropriate use; and

(iii) Procedures for disinfection of garments, supplies, equipment, and waste.

(o) *CDC-registered animal care facility standard operating procedures, requirements, and equipment standards for crating, caging, and transporting live animals.* (1) Equipment standards for crating, caging, and transporting live animals must be in accordance with USDA Animal Welfare regulation standards (9 CFR parts 1, 2, and 3) and International Air Transport Association standards.

(2) Animals must not be removed from crates during transport.

(3) Used PPE, bedding, and other potentially contaminated material must be removed from the ground transport vehicle upon arrival at the animal care facility and disposed of or disinfected in a manner that would destroy potential pathogens of concern.

(p) Health reporting requirements for animals at CDC-registered animal care facilities.

(1) A CDC-registered animal care facility must provide the following services for each animal upon arrival and ensure each animal meets CDC entry requirements prior to release from the facility:

(i) Veterinary examination by a USDA-accredited veterinarian within one business day of arrival;

(ii) Verification of microchip and confirmation that the microchip number matches the animal's health records;

(iii) Verification of animal's age via a dental examination;

(iv) Revaccination against rabies using a USDA-licensed vaccine; and

(v) Verification of a valid serology test from a CDC-approved laboratory drawn from a dog prior to arrival within a timeframe and results within parameters as specified in CDC technical instructions or 28-day quarantine after administration of the USDA-licensed rabies vaccine.

(2) A CDC-registered animal care facility must provide the following services upon the occurrence of any morbidity or mortality in an imported animal in the facility:

(i) Notification to CDC within 24 hours of the arrival of an ill animal or occurrence of any illness or death occurring in an animal.

(ii) Examination by a USDA-accredited veterinarian immediately upon detection of illness and diagnostic testing to determine the cause of illness. All costs associated with examination and diagnostics are the responsibility of the importer.

(iii) Reporting of suspected or confirmed zoonotic diseases and ecto-parasites to CDC and the State or county public health veterinarian within 24 hours of identification. Suspected or

confirmed foreign animal diseases or infectious animal diseases must be reported to USDA and the State or county veterinarian within 24 hours of identification.

(iv) Necropsy and diagnostic testing to determine the cause of death. The importer is responsible for all costs associated with necropsy and testing.

(3) Upon completion of the quarantine period and before a facility releases any animal from quarantine, the facility must ensure that the facility's USDA- accredited veterinarian has verified the health status of the animal and all required paperwork is uploaded into SAFE TraQ.

(4) Any report required under this paragraph must be uploaded to SAFE TraQ prior to the release of the animal.

(q) *Quarantine requirements for animals at CDC-registered animal care facilities.* (1) A CDC-registered animal care facility must maintain a quarantine area for holding dogs during the required quarantine period. Dogs must be quarantined for 28 days after revaccination with a USDA-licensed rabies vaccine at the facility if they do not have a valid rabies serologic test from a CDC-approved laboratory. CDC may extend the quarantine period if a facility or CDC finds or suspects that a dog is infected with, or has been exposed to, a zoonotic disease or if a facility or CDC determines that additional diagnostic testing is warranted.

(2) For any quarantine area established or maintained under this section, a facility must establish, implement, maintain, and adhere to standard operating procedures that meet the following physical security requirements:

(i) The CDC-registered animal care facility must be locked and secure, with access limited to authorized, trained, and knowledgeable personnel.

(ii) A CDC-registered animal care facility must limit access to animal quarantine areas to authorized personnel responsible for the transport, care, or treatment of the animals.

(3) During the quarantine period, a CDC-registered animal care facility must monitor animals for signs of any zoonotic illness, including, but not limited to, signs consistent with rabies, brucellosis, leptospirosis, leishmaniasis, or ecto- or endo-parasites.

(4) If any animals appear ill during quarantine, the CDC-registered animal care facility must notify CDC through SAFE TraQ and monitor that animal for signs of zoonotic illness and ensure appropriate treatment. Suspected or confirmed zoonotic diseases in animals or facility workers must be reported to CDC within 48 hours.

(5) A CDC-registered animal care facility must not knowingly release any ill animal from quarantine under paragraph (q)(3) of this section without prior consultation with and written approval from CDC.

(6) Quarantined animals must be housed in such a manner that they do not expose non-quarantined animals (including an animal other than a dog or cat) to other potentially infectious materials, including soiled bedding, caging, and other potentially contaminated items.

(7) If CDC notifies a CDC-registered animal care facility of any evidence that animals have been exposed to a zoonotic disease, the facility must, at the facility's expense, implement or cooperate in the CDC's implementation of additional measures to rule out the spread of suspected zoonotic disease before releasing an animal or shipment of animals from quarantine, including examination, additional diagnostic procedures, treatment, detention, isolation, seizure, or destruction of exposed animals.

(8) A CDC-registered animal care facility must establish, implement, and adhere to standard operating procedures for safe handling and necropsy of any animal that dies in quarantine.

(r) Revocation and reinstatement of a CDC-registered animal care facility's registration.

(1) If the Director determines that a CDC-registered animal care facility has failed to comply with any applicable provisions of this section, including failure to abide by the facility's standard operating procedures, the Director may revoke the facility's registration.

(2) CDC will send the CDC-registered animal care facility a notice of revocation stating the grounds upon which the proposed revocation is based.

(3) If the CDC-registered animal care facility wishes to contest the revocation, the facility must file a written response to the notice within five business days after receiving the notice.

(4) As part of the response, a CDC-registered animal care facility may request that the Director review the written record.

(5) If a CDC-registered animal care facility fails to file a response within five business days, all of the grounds listed in the proposed revocation will be deemed admitted, in which case the notice shall constitute final agency action.

(6) If a CDC-registered animal care facility's response is timely, the Director will review the registration, the notice of revocation, and the response, and make a decision in writing based on the written record.

(7) As soon as practicable after completing the written record review, the Director will issue a decision in writing that shall constitute final agency action. The Director will provide the facility with a copy of the written decision.

(8) The Director may reinstate a revoked registration after inspecting the facility, examining its records, conferring with the facility, and receiving information and assurance from the facility of compliance with the requirements of this section.

(s) Requirement for the CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States form to import foreign-vaccinated dogs from DMRVV high-risk countries. (1) Importers of foreign-vaccinated dogs from DMRVV high-risk countries must submit the CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States form to the CDC-registered animal care facility in order to make a reservation at that facility.

(2) Importers must present documentation confirming the dog's reservation at a CDC-registered animal care facility to the airline prior to boarding and to CBP upon arrival at a U.S. port for admission of foreign-vaccinated dogs from DMRVV high-risk countries.

(3) The CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States form must be truthful and accurate, completed in English, and include:

(i) The name of person importing the dog (consignee), physical address, phone number, email address, passport number and date of birth;

(ii) The owner's name, phone number, and email address;

(iii) The destination address (physical address) where the dog will reside upon arrival in the United States;

(iv) The dog's name, microchip number, microchip implant date, breed, sex, date of birth or approximate age if the date of birth is unknown, and color or markings of the dog;

(v) Rabies vaccination information for the dog administered within a timeframe and in accordance with the vaccination schedule as specified in CDC technical instructions;

(vi) Rabies vaccine product information (product name, manufacturer, lot number, and product expiration date);

(vii) Rabies vaccine expiration date (date when next vaccine is due), which must be after the dog's date of arrival at a U.S. port;

(viii) The name, license number or official stamp, address, telephone number, email address, and signature of the authorized veterinarian or official government veterinarian that examined the dog in the exporting country; and

(ix) The name, address, official seal or stamp, and signature of an official government veterinarian attesting that the authorized veterinarian is licensed or authorized to practice veterinary medicine in the exporting country and further attesting that the information listed on the form is true and correct.

(4) Importers who fail or refuse to present the CDC Import Certification of Rabies Vaccination and Microchip Required for Live Dog Importations into the United States form or

present a form that is untruthful, inaccurate, and incomplete may result in the dog denied admission and returned to the country of departure pursuant to paragraph (v) of this section.

(t) *Requirement for Certification Of U.S.-Issued Rabies Vaccination for Live Dog Re-entry into the United States form for importers seeking to import U.S.-vaccinated dogs from DMRVV high-risk countries.* (1) Importers returning to the United States from a DMRVV high-risk country with their U.S.-vaccinated dog may present their dog for admission without a rabies serologic test from a CDC-approved laboratory, without the dog undergoing veterinary examination (unless ill, injured, or exposed), and without revaccination against rabies at a CDC-registered animal care facility upon arrival under the following circumstances:

(i) The importer presents a Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States form that is truthful, complete, and accurate.

(ii) The dog must arrive by air and entry must be made through a U.S. airport with a CDC quarantine station.

(iii) The importer presents a valid Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States form that sufficiently and reliably demonstrates that a USDA-licensed rabies vaccine was administered within a timeframe and age parameters as specified in CDC technical instructions.

(2) The Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States form must be completed prior to the dog leaving the United States and cannot be completed upon arrival at a U.S. port or after the dog has left the United States.

(3) Importers returning to the United States from a DMRVV high-risk country with their U.S.-vaccinated dog that are unable to meet the requirements of this paragraph (t) shall have the dog treated as if it was vaccinated in a foreign country in accordance with the provisions of paragraph (k) of this section and this paragraph (t) or, alternatively, have the dog denied admission and returned to the country of departure pursuant to the paragraph (v) of this section.

(4) If an importer fails to immediately (within 24 hours of arrival) arrange for the dog's return to the country of departure, then the animal will be considered abandoned pursuant to paragraph (z) of this section.

(u) *Requirement for proof that a dog has only been in a DMRVV low-risk or DMRVV-free country.* Dogs arriving, including those returning to the United States, from a DMRVV low-risk or DMRVV-free country may be admitted into the United States subject to the requirements in this section if the importer submits written documentation (i.e., veterinary records, veterinary import/export certificate) satisfactory to the Director that for the six months before arrival, the dog has been only in a DMRVV low-risk or DMRVV-free country.

(v) *Denial of admission of dogs and cats.* (1) The Director may deny admission to the following categories of animals:

(i) Any dog arriving from a DMRVV low-risk or DMRVV-free country without written documentation (i.e., veterinary records, veterinary import/export certificate) that the dog has only been in a DMRVV low-risk or DMRVV-free country for the six months prior to the attempted entry, or if the Director reasonably suspects fraud.

(ii) Any dog that is not accompanied by a receipt confirming that a CDC import submission form has been submitted to CDC through a CDC-approved system.

(iii) Any dog arriving by air for which a bill of lading has not been created by the airline prior to arrival.

(iv) Any dog arriving by land to the United States from DMRVV high-risk countries.

(v) Any dog arriving by sea to the United States from DMRVV high-risk countries, except for a dog qualifying as a service animal and meeting the standards set forth in paragraph (d)(4) of this section.

(vi) Any dog imported by an importer who refuses to comply with the requirement (if applicable) to undergo disease surveillance screening, microchip scanning, veterinary examination, revaccination, provide proof of sufficient rabies serologic tests, or quarantine at a

CDC-registered animal care facility or other CDC-approved facility (if a CDC-registered Animal Care Facility is not available) upon arrival.

(vii) Any dog that has been in a DMRVV high-risk country in the previous six months and arrives without a valid Certification of U.S.-issued Rabies Vaccination for Live Dog Re-entry into the United States form or a valid CDC import certification of rabies vaccination and microchip required for live dog importations into the United States form.

(viii) Any dog that has been in a DMRVV high-risk country in the previous six months and does not arrive via air at a U.S. airport with a CDC quarantine station and a CDC-registered animal care facility, except for a dog arriving by sea that qualifies as a service animal and meets the standards set forth in paragraph (d)(4) of this section.

(ix) Any dog imported from a DMRVV high-risk country that arrives without a reservation at a CDC-registered animal care facility (if applicable).

(x) Any dog from a DMRVV-restricted country that arrives without a valid CDC dog import permit.

(xi) Any dog imported from a DMRVV high-risk country if the Director reasonably suspects fraud in any documentation required for admission or if such documentation is otherwise untruthful, inaccurate, or incomplete.

(xii) Any animal, regardless of country of departure, that poses a public health risk, including animals that appear unhealthy upon arrival or demonstrate signs or symptoms of communicable disease.

(xiii) Any dog under six months of age that is arriving via air or sea into the United States, or any dog under six months of age imported via a land port if the importer has imported more than three individual dogs under six months of age in the same calendar year (January-December).

(2) Animals arriving by air that are awaiting an admissibility determination or denied admission must be held in CDC-registered animal care facilities or other CDC- or USDA-

approved veterinary clinics (if a CDC-registered animal care facility is not available) in such a way as to prevent the potential spread of communicable diseases.

(3) Pursuant to 9 CFR 3.14(f), animals arriving by air that are denied admission must be transported to a CDC-registered animal care facility (or other boarding, kennel, or veterinary clinic approved by CDC if a CDC-registered animal care facility is not available) by the airline within six hours of denial of admission into the United States while awaiting return to the country of departure, excluding animals transiting through the United States. Animals arriving by sea that are denied admission must remain on the vessel while awaiting return to the country of departure.

(4) An importer must meet the admission requirements of all U.S. Government agencies for the admission of an animal into the United States. Satisfaction of CDC's requirements for the admission of animals does not fulfill the admission requirements of other U.S. Government agencies.

(w) *Disposal or disposition of dogs and cats denied admission to the United States.* (1) Animals shall be subject to such additional requirements, including denial of admission, as may be deemed necessary by the Director to protect the public's health or suspension of entry under 42 CFR 71.63.

(2) Animals denied admission to the United States that were transported to the United States via air must be returned by the airline to the country of departure at the importer's expense on the next available outbound flight (no later than 72 hours after arrival), regardless of airline or route, if fit to travel. Pending the animal's return, the animal shall be detained at the importer's expense in the custody of the carrier at a CDC-registered animal care facility (or other boarding, kennel, or veterinary clinic approved by CDC if a CDC-registered animal care facility is not available).

(3) Animals denied admission to the United States that were transported to the United States via sea shall be reembarked immediately by the vessel's master or operator and returned to its country of departure on the next voyage.

(4) Animals denied admission to the United States that were transported to the United States via land shall be returned immediately by importer or carrier to their country of departure.

(5) If an animal is not fit to travel, poses a public health risk, or would pose a risk to other animals, then the carrier shall arrange for the animal to be transported to a CDC-registered animal care facility or a CDC- approved veterinary clinic (if a CDC-registered animal care facility is not available) for either housing and treatment by a licensed veterinarian until approved for travel by CDC or humanely euthanized (e.g., under circumstances where the animal is fatally ill or injured) by a licensed veterinarian. The importer shall be responsible for all costs associated with the denial, veterinary evaluation, care, or disposal of the animal. If the importer refuses to pay for any costs associated with the denial, evaluation, care, or disposal of the animal, then it will be considered abandoned, and the carrier shall assume custody and financial responsibility for these costs.

(6) If humane euthanasia is recommended by a veterinarian or chosen by an importer or carrier (e.g., under circumstances where the animal is fatally ill or injured), the animal must be euthanized by a U.S.-licensed veterinarian in accordance with American Veterinary Medical Association guidelines. Euthanasia does not relieve carriers or importers of the obligation to arrange and pay for testing and necropsy required by CDC.

(7) The Director may grant temporary extensions of returns for animals that are not fit for travel as determined by a CDC veterinarian, but the importer (or carrier in the case of abandonment) must arrange for the return of the animal to its country of departure as soon as CDC notifies the carrier that the animal is fit for travel.

(8) The requirements of this paragraph shall additionally apply to dogs or cats abandoned by the importer prior to the dogs' or cats' admission into the United States. A dog or cat may be deemed abandoned pursuant to the provisions of paragraph (z) of this section.

(9) Carriers must provide transportation to/from and holding at a CDC-registered animal care facility (or other boarding, kennel, or veterinary clinic approved by CDC if a CDC-registered animal care facility is not available) while determining admissibility, undergoing veterinary evaluation or care, or upon denial of entry. Carriers may require reimbursement from an importer for any costs incurred on behalf of the importer.

(10) Importers must comply with CDC requirements for the return of an animal or for the veterinary assessment of an animal. Refusal to cooperate, including refusal to pay any associated veterinary fees, will result in the animal being considered abandoned by the importer, and custody of the animal will be transferred to the carrier who will assume financial responsibility for costs relating to the denial, evaluation, care, or disposal of the animal.

(11) A carrier may enter into contractual arrangements with an importer or a third party relating to the expenses of returning an animal to its country of departure, for veterinary care, or otherwise disposing of an animal, provided that no government costs are incurred. The return of an animal to its country of departure or the initiation of veterinary care shall not be delayed while the carrier attempts to enter into or negotiate contractual arrangements.

(12) The provisions of this paragraph may be applied to importers of animals and to carriers transporting such animals in circumstances where an animal is denied entry at a land port or seaport of the United States and the animal cannot be immediately returned to its country of departure (e.g., because it is unfit to travel).

(x) Appeals of CDC denials to admit a dog or a cat upon arrival into the United States.

(1) If CDC denies admission to an animal upon arrival, then the importer may appeal that denial to the Director.

(2) The importer must submit the appeal in writing to the Director, stating the reasons for the appeal and demonstrating that there is a genuine and substantial issue of fact in dispute.

(3) The importer must submit the appeal within one (1) business day of the denial by emailing CDCAnimalImports@cdc.gov.

(4) Submitting an appeal will not delay the return of the animal to the country of departure.

(5) The Director will issue a written response to the appeal, which shall constitute final agency action.

(y) *Record of death of dogs and cats en route to the United States and disposition of dead animals.* (1) Carriers shall maintain a record of the death of animals occurring while *en route* to the United States and shall submit the record to the CDC quarantine station of jurisdiction for the U.S. port upon arrival.

(2) Animals that become sick or die en route or are identified as sick or dead upon arrival shall be separated from other animals (including animals other than dogs or cats) as soon as the sickness or death is discovered and shall be held in confinement pending any necessary examination as determined by the Director. Sick animals shall be examined pursuant to the provisions of paragraph (j) of this section or disposed of pursuant to the provisions of paragraph (w) of this section.

(3) The carrier shall arrange for any animals that die en route to the United States or that die while detained pending determination of their admissibility to undergo a necropsy (gross and histopathologic examination are required), and any subsequent infectious disease testing based on gross or histopathology findings or as determined by CDC. The carrier or CDC-registered animal care facility must contact the CDC quarantine station of jurisdiction prior to transporting an animal for necropsy to determine whether rabies testing is required. In the event an importer abandons an animal, the carrier will become the owner and shall assume responsibility for all expenses described in this paragraph (y)(3).

(4) The carrier shall send copies of the final necropsy report and all test results to the CDC quarantine station of jurisdiction.

(5) Pursuant to paragraphs (p) and (w) of this section, the importer is responsible for costs associated with the necropsy, testing, and disposal of the body. In the event an importer abandons an animal, then pursuant to paragraph (z) of this section, the carrier will become the owner and shall assume responsibility for all expenses described in paragraph (y)(3) of this section.

(z) *Abandoned shipments of dogs and cats.* (1) In the event an importer abandons an animal under this section, the carrier will become the owner and shall assume responsibility for all expenses described in this section.

(2) An animal shipment will be deemed abandoned under the following circumstances:

(i) When explicitly stated by the importer verbally or in writing to the carrier, CDC, or CBP; or

(ii) If the importer fails to cooperate with or respond to the carrier's attempts to comply with the provisions of this section within 24 hours; or

(iii) If the importer refuses payment within 24 hours for CDC-mandated examinations, testing, holding, or treatment needed to ensure the safe importation of dogs and cats into the United States.

(aa) *Sanitation of cages and containers of dogs and cats.* When the Director finds that the cages or other containers of animals arriving in the United States are in an unsanitary or other condition that may constitute a communicable disease risk, the animals shall not be admitted in such containers unless the carrier has the containers cleaned and disinfected or the animals are removed and placed in clean containers in accordance with USDA and, in the case of airlines, the International Air Transport Association (IATA) shipping requirements. Discarded containers must be cleaned and disinfected or destroyed in accordance with carrier policies. CDC may require documentation of crate disinfection or destruction by the carrier.

(bb) *Requirements for in-transit shipments of dogs and cats.* (1) In-transit shipments of live animals are not eligible for release into the United States.

(2) In-transit shipments must be maintained under continuous confinement with USDA APHIS oversight onboard a conveyance until export or off-loaded and maintained under continuous confinement and APHIS oversight at a USDA APHIS-preapproved holding facility with a CBP-issued FIRMS code while awaiting a connecting conveyance, and then loaded and maintained under USDA APHIS oversight onboard the connecting conveyance until export.

(3) The provisions of this section shall apply to animals transiting through the United States from one foreign country to another, except as provided in paragraphs (bb)(3)(i) and (ii) of this section:

(i) Animals that appear healthy but have been exposed to a sick or dead animal (including an animal other than a dog or cat) suspected of having a communicable disease are not required to undergo examination or tests as provided in paragraph (j) of this section if the Director determines that the conditions under which the animals are being transported afford adequate protection against introduction of communicable disease into the United States.

(ii) The CDC Import Certification of Rabies Vaccination and Microchip Required For Live Dog Importations into the United States form or Certification Of U.S.-Issued Rabies Vaccination For Live Dog Re-entry into the United States form is not required for dogs that are transported by aircraft and are being transited through the United States if retained in the custody of the airline under conditions that would prevent transmission of communicable diseases.

(cc) *Bill of lading and other airline requirements for dogs.* (1) Airlines are required to create a bill of lading for all dogs arriving in the United States prior to arrival. This includes dogs transported as cargo, checked-baggage, or hand-carried baggage.

(2) Dogs arriving by air for which a bill of lading has not been filed prior to arrival in the United States may be denied admission and returned to the country of departure pursuant to paragraph (v) of this section.

(3) Airlines must deny boarding to any dogs for which the importer has not presented to the airline before boarding a receipt confirming submission of the CDC import submission form. Airlines must also deny boarding if the dog presented for travel does not match the description on the receipt of the CDC import submission form.

(4) For U.S.-vaccinated dogs that have been in a DMRVV high-risk country within the last six months, airlines must deny boarding unless the importer presents prior to boarding a valid certification of U.S.-issued rabies vaccination for live dog re-entry into the United States form. Airlines must also deny boarding if the dog presented for travel does not match the description on the Certification of U.S.-Issued Rabies Vaccination for Live Dog Re-entry into the United States form or if the dog is scheduled to arrive in the United States at a U.S. airport that does not have a CDC quarantine station.

(5) For foreign-vaccinated dogs that have been in a DMRVV high-risk country within the last six months, airlines must deny boarding unless the importer presents documentation to the airline before boarding of a reservation at a CDC-registered animal care facility and the dog is scheduled to arrive in the United States at the U.S. airport where the CDC-registered animal care facility is located.

(6) For dogs from DMRVV-free or low-risk countries, airlines must deny boarding unless the importer presents documentation to the airline before boarding by showing that the dog is over six months of age, has a microchip, and has not been in a DMRVV high-risk country in the previous six months. Airlines must also deny boarding if the dog presented for travel does not match the description on the documents presented by the importer for travel.

(7) A representative of an airline transporting live dogs into the United States must be on-site at the U.S. airport and available to coordinate the entry/clearance of the dogs with Federal Government officials until all live dogs transported on an arriving flight into the United States have either been cleared for entry or arrangements have been made to transport the dogs to a

CDC-registered animal care facility or other facility (e.g., veterinary clinic or kennel) approved by CDC pending an admissibility determination.

(dd) *Order prohibiting carriers from transporting dogs and cats.* (1) If the Director determines that a carrier has endangered the public health of the United States by acting or failing to act to prevent the introduction of DMRVV, as would occur through failure to comply with any applicable provisions of this section, the Director may issue an order revoking the carrier's permission to transport live animals into the United States, which shall be served on the carrier's owner or operator.

(2) The Director may rescind the order after inspecting the carrier's facilities; examining its records; conferring with the carrier's owners or operators, its contractors, or staff; or receiving information and written assurances from the carrier owner or operator that it has taken remedial steps to ensure future compliance with the requirements of this section.

(3) A carrier owner or operator may appeal a revocation of a carrier's permission to transport live animals into the United States. The appeal shall be in writing, addressed to the Director, state the reasons for the appeal, and demonstrate that there is a genuine and substantial issue of fact in dispute. The appeal must be submitted via email to CDCAAnimalImports@cdc.gov

(4) As soon as practicable after completing the appeal review, the Director will issue a decision in writing that shall constitute final agency action. The Director will serve the carrier with a copy of the written decision.

(ee) *Prohibition on imports of dogs from DMRVV-restricted countries.* (1) The Director may prohibit or otherwise restrict the import of dogs into the United States from certain countries designated as DMRVV-restricted countries. CDC will maintain a list of DMRVV-restricted countries for which the import of dogs into the United States has been prohibited or otherwise restricted based on the countries' prior export of dogs infected with DMRVV to any other countries within a time frame determined by CDC or based on inadequate controls, as determined by CDC, in the countries to monitor and prevent the export of dogs to the United

States with falsified or fraudulent rabies vaccine credentials, invalid rabies vaccination certificates, or other fraudulent, inaccurate, or invalid exportation/importation documents.

(2) DMRVV-restricted countries may be subject to additional restrictions, including a complete prohibition on the importation of dogs into the United States from those countries as needed to prevent the reintroduction of DMRVV.

(3) The Director may maintain such additional restrictions or prohibitions in place until the Director is satisfied that the DMRVV-restricted country has established sufficient controls to prevent the reintroduction of DMRVV into the United States, including measures to prevent the use of falsified or fraudulent vaccine credentials or invalid rabies vaccination certificates.

(4) The addition or removal of DMRVV-restricted countries from the list shall be announced through notification in the *Federal Register*, and a list will be maintained on CDC's website.

(5) Notwithstanding the prohibition on imports of dogs from DMRVV-restricted countries, the Director may allow the importation of dogs for scientific purposes, when used as a service animal (as defined in 14 CFR 382.3) for individuals with disabilities, or in furtherance of an important government interest. In such instances CDC will issue a CDC dog import permit for the importation of dogs from DMRVV-restricted countries. Instructions for how to apply for a permit will be included in CDC technical instructions.

(ff) *Request for issuance of additional fines or penalties.* CDC may request that U.S Customs and Border Protection (CBP), pursuant to 19 U.S.C. 1592 and 19 U.S.C. 1595a, issue additional fines, citations, or penalties to importers, brokers, or carriers when the Director has reason to believe that an importer, broker, or carrier has violated any of the provisions of this section or otherwise engaged in conduct contrary to law.

Dated: June 30, 2023

Xavier Becerra,

Secretary, Department of Health and Human Services

